

**A COMPARATIVE STUDY ON PROLONGED ENDOTRACHEAL
INTUBATION VERSUS TRACHEOSTOMY IN TOXICOLOGY ICU
PATIENTS REQUIRING PROLONGED MECHANICAL
VENTILATION**

*Dissertation submitted in partial fulfillment of the regulations
for the award of the degree of*

**M.S.DEGREE OTORHINOLARYNGOLOGY
BRANCH - IV**



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BONAFIDE CERTIFICATE

This is to certify that this dissertation work entitled “**A COMPARATIVE STUDY ON PROLONGED ENDOTRACHEAL INTUBATION VERSUS TRACHEOSTOMY IN TOXICOLOGY ICU PATIENTS REQUIRING PROLONGED MECHANICAL VENTILATION**” is the original bonafide work done by **DR.G.PARIMALA DEVI**, Post Graduate Student, Upgraded institute of otorhinolaryngology, Madras Medical College, Chennai under our direct supervision and guidance.

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ABBREVIATION

GCS	-	GLASGOW COMA SCALE
D.O.INT	-	DATE OF INTUBATION
D.O.TRACH	-	DATE OF TRACHEOSTOMY
PROL.INT	-	PROLONGED INTUBATION
ET	-	EARLY TRACHEOSTOMY
LT	-	LATE TRACHEOSTOMY
D.O.DIS	-	DATE OF DISCHARGE
D.O.WEAN	-	DATE OF WEANING
REINT	-	REINTUBATION
IOC	-	INTRA OPCOMPLICATIONS
D.O.W.A.TRACH	-	DATE OF WEANING AFTER TRACHEOSTOMY
D.O.TR	-	DATE OF TRANSFER OUT
VDL 1ST VISIT	-	WITHIN 1 MONTH AFTER DISCHARGE
VDL SECOND VISIT	-	DONE AT SIX MONTHS AFTER DISCHARGE
VAP	-	VENTILATOR ASSOCIATED PNEUMONIA

Introduction

INTRODUCTION

Tracheostomy is the most frequently performed procedure in critically ill patients. It is done in patients requiring prolonged ventilation. The benefits of tracheostomy over prolonged intubation are: lessen use of sedation, less trauma to the oropharynx and larynx, reduced work of breathing and improved clearance of secretions from airway, shorten periods of mechanical ventilation and eventually decreased length of ICU and hospital stay.

Patients, who had prolonged tracheal intubation and consequently some of them had late tracheostomy, had more complications; airway injuries and ventilator-associated pneumonia than those who underwent early tracheostomy.

The main purpose of our study is to assess if tracheostomy compared to prolonged intubation decreases the mean duration of ventilation, the incidence of nosocomial pneumopathy, the mean duration of hospitalisation in the ICU ward and mortality rate. To also assess the benefits of early versus late tracheostomy and also to stress upon the risks associated with prolonged translaryngeal intubation.

A tracheotomy is a creation of a surgical opening in the trachea, whereas a tracheostomy is the creation of a stoma at the skin surface of the neck which leads into the tracheal lumen.

TYPES OF TRACHEOSTOMY¹

1. Temporary Tracheostomy

Elective tracheostomy is done in cases of prolonged ventilation or prior to any major surgical procedures which can predispose to upper airway obstruction whereas emergency tracheostomy is done in cases of laryngo tracheal trauma or malignancy of upper aerodigestive tract to relieve stridor

2. Permanent Tracheostomy

Also called end tracheostomy is done as a part of total laryngectomy or laryngopharyngectomy.

Also done in laryngeal diversion procedures to overcome aspiration

EFFECTS OF A TRACHEOSTOMY¹

1. Laryngeal bypass – loss of cough and speech
2. Lessen respiratory dead space;
3. Loss of nasal mucosa filtration and humidification;
4. Increased risk of infection
5. Tube behaves as a foreign body leading to adjacent skin inflammation;
6. Behaves like a sump above tracheostome and below vocal cords, where mucus accumulates.

INDICATIONS OF TRACHEOSTOMY¹

1.PROLONGED VENTILATION

Tracheostomy is the safest means of supporting ventilation where prolonged positive pressure is required. It is easier to place a tracheostomy tube than an endotracheal tube (through nasal or oral route) and the decreased dead space helps in early weaning of ventilator support.

It has been analysed that ease of access to tracheostomy has resulted in reduced duration of endotracheal intubation. With the launch of low pressure cuffs for endotracheal tubes, a longer period of intubation has become possible.

There is evidence that early tracheostomy in trauma patients shortens the length of ventilation and hospital stay.

2.REMOVAL OF SECRETIONS

The accumulation of secretions in the lower airway tract is responsible for a decrease in gas diffusion within the alveoli. This ends in respiratory failure.

A tracheostomy thus reduces the dead space, so decreasing the work of breathing and also helps to aspirate secretions with less discomfort to the patient.

3.AS A PART OF ANOTHER PROCEDURE

A temporary tracheostomy should be considered as mandatory for all major surgical procedures involving the oral cavity or pharynx. In all these cases, the tracheostomy helps protection of the lower respiratory tract from aspiration of

blood, in the event of bleeding , as well as protecting against upper airway obstruction from postoperative oedema.

4.UPPER AIRWAY OBSTRUCTION

When meeting a patient with upper airway obstruction, other co existing medical ailments should be carefully assessed. It is important to determine the exact level of obstruction so that tracheostomy provides relief at the lowest level of obstruction¹

HISTORY OF TRACHEOSTOMY²

100 AD: Antyllus did the first familiar tracheostomy: a horizontal incision between 2 tracheal rings to overcome upper airway obstruction.

131 AD: Galen described laryngeal and tracheal anatomy. He was the first to identify and localize voice production to the larynx and to describe laryngeal innervation. He also described the importance of supralaryngeal airway tract in respiration (e.g.warming, humidifying and filtering of inspired air).

400 AD: The Talmud put forth longitudinal incision in order to reduce bleeding.

600 AD: The Sushruta Samhita contained routine acknowledgment of tracheostomy as accepted surgical procedure in India.

During the 11th century, Albucasis of Cordova Succeeded in suturing the trachea of a servant who attempted suicide by cutting her throat.

1546: The first record of a tracheotomy was done in Europe in the 16th century by Antonius Musa Brasavola. He was an Italian physician. He saved a patient diagnosed to have laryngeal abscess in severe stridor. The patient improved well after the procedure. Later, he published an article of tracheostomy for tonsillar obstruction. He was the first person known so far to perform a tracheostomy.

1718: Lorenz Heister coined the term tracheotomy, which was prior called as laryngotomy or bronchotomy.

1739: Francis Home elucidated an upper airway inflammation as Croup, and advised tracheostomy to relieve obstructed airway.

1800-1900: Before 1800 only 50 life-saving tracheotomies are seen in the literature

In 1805 Viq d'Azur described cricothyrotomy. An eye opener in tracheostomy developed after Napoleon Bonaparte's nephew expired of diphtheria in 1807

During the diphtheria epidemic in France in 1825, tracheostomies gained further importance

Further refinements followed:

1833: Trousseau stated 200 patients with diphtheria Cured with tracheostomy.

In 1852, Bourdillat discovered a primitive pilot tube;

In 1869 Durham described the famous lobster-tail tube;

1880 parker introduced the first pediatric tracheostomy

Later, description of endotracheal intubation was made in the early 20th century

1909: Chevalier Jackson standardized the technique of surgical tracheostomy and published the operative details of this procedure.

He described the indications and techniques for modern tracheostomy and cautioned of complications of high tracheostomy and cricothyroidotomy.



Chevalier Q Jackson who described steps of tracheostomy

Fig -1, Courtesy-principles and practice of percutaneous tracheostomy

1932: Wilson advised prophylactic tracheostomy in patients with poliomyelitis to facilitate the removal of airway secretions.

Mid 1800s to 1970 -metallic tracheostomy tubes were used abundantly. These tubes were associated with increased rate of tracheal complications and aspiration pneumonia.



Fig -2 courtesy-principles and practice of percutaneous tracheostomy
Metallic tracheostomy tube with plain and fenestrated inner cannulas.

Tredenlenburg, in 1969, was the first one to propose cuff in a tracheostomy. Till middle of the year 1970,cuffs used were high pressure low volume cuffs. This led to lot of tracheal injuries. This eventually led to the description of high-volume, low pressure cuffs in tracheostomy tubes made of polyvinyl chloride or silicone.

These cuffs when inflated lead to larger surface area for contact with the windpipe, therefore reducing the occurrence of tracheal mucosal ischemia and necrosis.

Seldinger in 1953 described the technique of guide wire needle replacement in percutaneous arterial catheterization; the same principle has been applied in percutaneous tracheostomy.

ANATOMY²

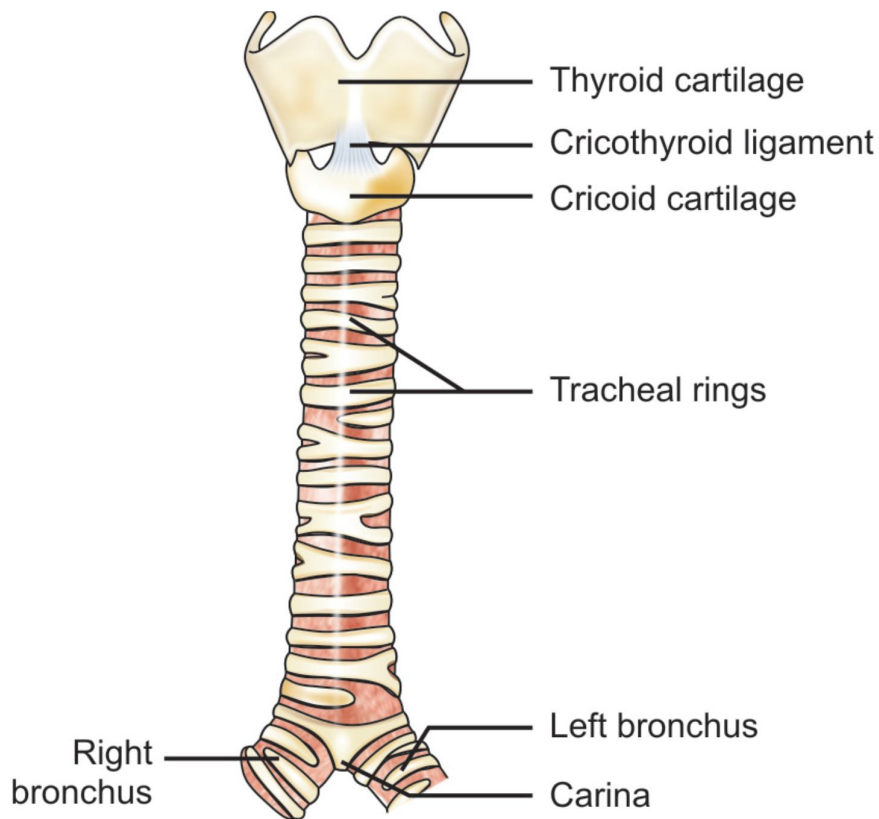


Fig 3 courtesy-principles and practice of percutaneous tracheostomy

The trachea or windpipe is a cartilaginous membranous tubular structure that is situated mainly on the front of the neck in the median plane. The upper end of trachea is continuous with the lower end of the larynx extending from the lower border of cricoid cartilage to carina. The junction corresponds to the lower part of the body of C6 and cricoid cartilage. It ends at the level of 4th thoracic vertebra where it branches into left and right main bronchi ³

In the normal anatomical position, in general the length of the trachea ranges from 10–14cm in an adult, but it varies with age, sex and race; roughly

50% of trachea is above and 50% of it is below the suprasternal notch. Windpipe is flattened anteroposteriorly.

The trachea consists of 16-20 horizontal 'C' shaped cartilages which are connected posteriorly by the trachealis muscles. Vertically, these cartilages are connected to each other by fibro-elastic tissue and they have similar appearance of tyres piled one on top of the other.

The first and last tracheal cartilages are of different nature from the rest of cartilages. The first cartilage is broader than the rest, and often deviated at one end that is attached with the cricotracheal ligament with the lower border of cricoid cartilage. The last cartilage is thick and broad in the centre. Its lower border is extended into a triangular hook-shaped process which bends downwards and backwards. This extends between the two bronchi forming a ridge called carina. These anterior cartilages play an important role in providing the rigidity for maintaining the patency of the tube. These cartilages are enclosed by a perichondrium, which is continuous with a fibrous membrane between adjacent tracheal cartilages and also at the posterior aspect of the trachea where the cartilage is deficient.

The trachea is freely movable and can extend and shorten on deep inspiration and expiration. On extending the neck a larger portion of the trachea becomes extrathoracic and while flexing larger portion of trachea lies within the thoracic cage. In general on deep inspiration the carina may extend up to the level of T6.

The tracheal wall is made up of four layers: mucosal, submucosal, cartilage, and adventitial. The inner most layer, the mucosa, is lined by ciliated pseudo-stratified columnar epithelium with abundant goblet cells. Mucus secreted from these goblet cells helps to filter the inhaled particles of dust. The cilia beats in such a way that these particles are swept upward into the laryngopharynx. After which these particles are swallowed or coughed out. The submucosa is made up of loose connective tissue filled with glands that secrete mucus.

Relations of windpipe

Despite the trachea is a midline structure in the neck, the lower trachea is shifted to the right by the aortic arch. The cervical part of the trachea is covered in the anterior aspect with the skin next by the superficial and then the deep fasciae.

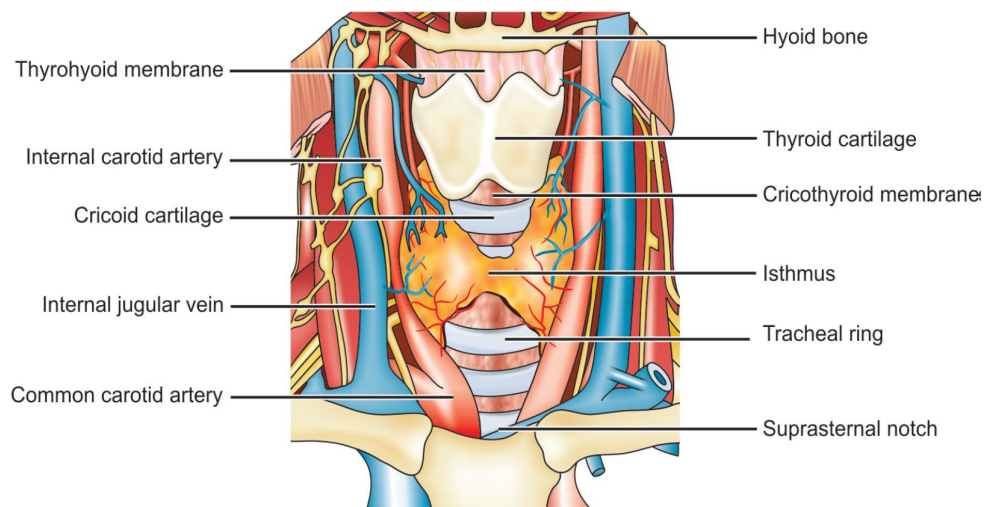


Fig 4 courtesy-principles and practice of percutaneous tracheostomy

The isthmus of the thyroid is situated at the level of the 7th cervical vertebra and runs across the 2nd, 3rd and 4th rings of the trachea. It is a highly

vascular structure, which on inadvertent damage during surgery or friction from the tracheostomy tube can lead to postoperative bleeding¹. Either side of the isthmus are occupied by the thyroid lobes.

Above and below the isthmus, there are two important structures. Above the isthmus there lies an anastomosing vessel connecting the two superior thyroid arteries. Below the isthmus it is related, anteriorly, to the pretracheal or the investing layer of deep cervical fascia, then the inferior thyroid veins, the remnants of the thymus and the thyroidea ima artery. Posteriorly, it is related to esophagus. The recurrent laryngeal nerves are found in both tracheoesophageal grooves running laterally.

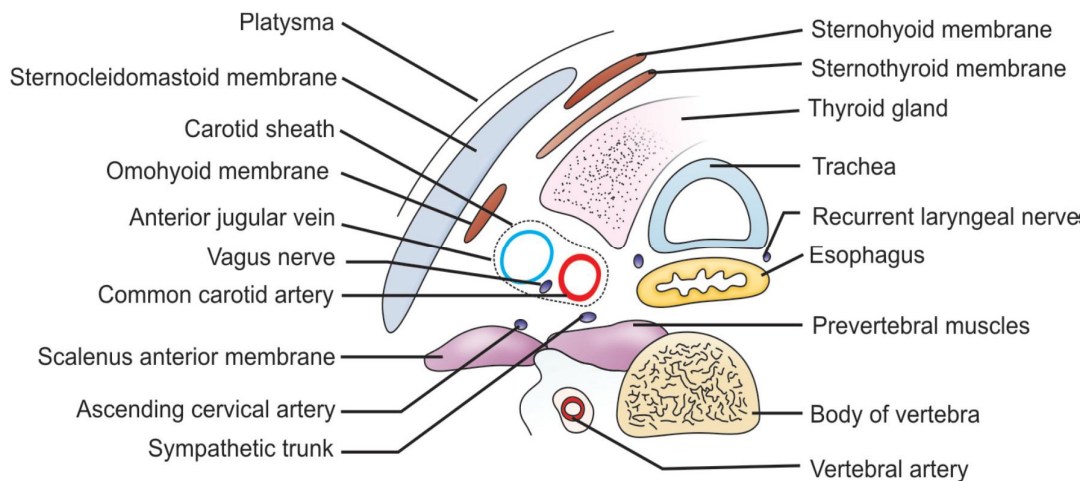


Fig 5 courtesy--principles and practice of percutaneous tracheostomy

At the suprasternal notch the thoracic trachea starts, entering the superior mediastinum. Here it lies just beneath the sternum.

The innominate artery, or brachiocephalic trunk, crosses from left to right in front of trachea at the level of superior thoracic inlet. In patients with high innominate artery, it can be damaged during dissection or suffer erosion from tube resulting in potentially fatal postoperative haemorrhage².

On the right side, the trachea is closely related laterally to the mediastinal pleura, the azygos vein and the vagus nerve. On the left side, it is related to the aortic arch and the major left sided arteries that come in between the trachea and pleura.

Hatfield and Bodenham concluded that two of their 30 patients had carotid arteries in the immediate paratracheal position, whereas another two patients had prominent brachiocephalic arteries. Fifty percent of the patients had anterior jugular veins .out of which eight were near the midline posing significant risk requiring appropriate ‘safety measures’.⁴

The recurrent laryngeal nerves and inferior thyroid veins are referred as paratracheal structures, which lie in the tracheoesophageal groove are vulnerable to injury if dissection extends laterally away from the midline. The carotid arteries and internal jugular veins could be easily damaged if dissection go far away from the field. This is a significant threat in obese or children.

VASCULAR AND NERVE SUPPLY²

The windpipe derives its vascular supply mainly from the inferior thyroid arteries. Its thoracic end is supplied in addition by the bronchial arteries, which give off branches ascending up to anastomose with the inferior thyroid vessels.

The veins from the trachea empty into the inferior thyroid venous plexus. The sensory innervation of trachea and vocal cords is from the recurrent laryngeal nerve which also convey sympathetic nerve endings from the middle cervical ganglion. The sensory supply of skin over the trachea is derived from the roots C2-C4 of cervical plexus.

Airway control needs a logical and systematic approach by following the principles of basic and advanced life support techniques and a working knowledge of relevant pharmacology. Most importantly, the health professional must hold a mastery of the anatomy and physiology of the laryngo tracheobronchial tree.⁵

CRICOTHYROIDOTOMY⁵

Cricothyroidotomy is a invasive method of airway management that was put forth by Brantigan and Grow in 1976⁹. The technique creates an opening into the cricothyroid membrane .It is then followed by the placement of a stenting tube. often cricothyroidotomy is the preferred method of obtaining an emergent entry into upper airway.⁶⁻⁸ The procedure starts with the identification of the cricothyroid space between the thyroid and cricoid cartilages. Local anesthesia may be infiltrated into the area if time permits. Over the middle third of the cricothyroid membrane, a horizontal incision is made and is carried straight away

into the airway. A dilating cannula is inserted next to the scalpel to secure the opening made in the cricothyroid membrane. Mayo scissors are then used to enlarge the surgical opening. Special care to be taken as not to damage the cricoid or thyroid cartilages. An endotracheal tube may be inserted through the cricothyroidotomy and ventilation initiated once the airway has been established, the patient may be shifted to the operating room. Then cricothyroidotomy may be repaired and converted to a tracheostomy.

Although this procedure has been used for long-term airway management, it is utmost useful in the emergency setting, where a surgical airway must be immediately gained.⁹ Cricothyroidotomy is faster and it is usually easier to perform than a tracheostomy, especially by a nonsurgeon, requiring little surgical skill other than a knowledge of anatomy. Some of the reported complications of cricothyroidotomy include bleeding, tube displacement, infection, true vocal cord damage, subcutaneous emphysema, and the development of subglottic or tracheal stenosis.^{10,11}

Hawkins et al confirmed the safety of emergency cricothyroidotomy in their series of 5,603 consecutive adult trauma patients, of whom 66 required cricothyroidotomy⁷. No significant morbidity or complications were noted in this series.

PERCUTANEOUS TRACHEOSTOMY

This procedure though employed commonly in western countries, it was first described by Ciaglia et al.¹⁴ The patient should be positioned as for a formal surgical tracheostomy with sand bag under shoulders. Then the windpipe is entered by puncturing with a needle and cannula, just below the first ring of tracheal cartilage. After which a syringe half filled with saline is attached to the cannula. On aspiration correct position of cannula is then confirmed, as air is aspirated through the saline when the needle plunges into the trachea. The needle is completely withdrawn and a guide wire is inserted through the cannula. This cannula is later withdrawn to allow for serial dilators to be inserted over the guide wire. Either single or graded dilators can be used. These dilators establish a wide passage for the proper positioning of a standard tracheostomy tube. It is advised to view the tracheal lumen with the help of flexible bronchoscope while doing this procedure to avoid complications.¹⁶

SURGICAL STEPS OF TRACHEOSTOMY

The patient should be made lying down in supine position with neck extension by placing a sandbag under the shoulders. While positioning care should be taken so that the shoulders are at the same level. This will let the midline structures of the neck to remain in the midline throughout the surgery.

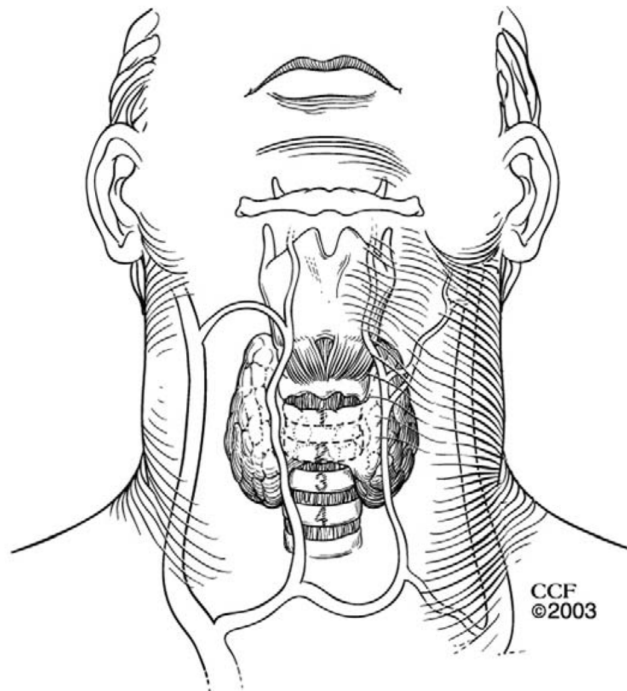


Fig 6 courtesy-clinics in chest medicine Techniques of surgical tracheostomy

While operating under local anaesthesia, care should be taken to prevent over extension which may further restrict the airway. A horizontal incision is made halfway between the sternal notch and the lower border of the cricoid cartilage.

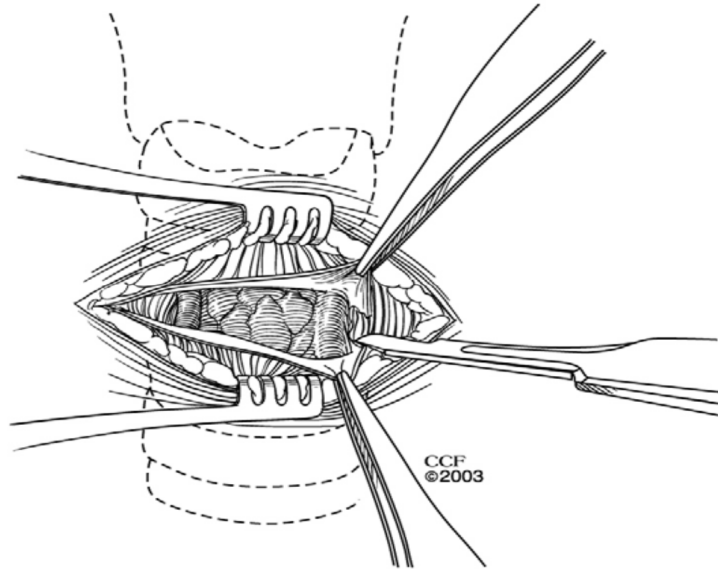


Fig 7 courtesy-clinics in chest medicine Techniques of surgical tracheostomy

Skin, subcutaneous tissue layers are dissected then the strap muscles are retracted laterally, by doing blunt dissection in the midline to separate them. Next to be seen is the thyroid isthmus.



Fig 8 courtesy-international article Tracheostomy: Why, When, and How?

The isthmus should be clamped, divided and transfixed¹. After doing that, the anterior tracheal wall comes into view.

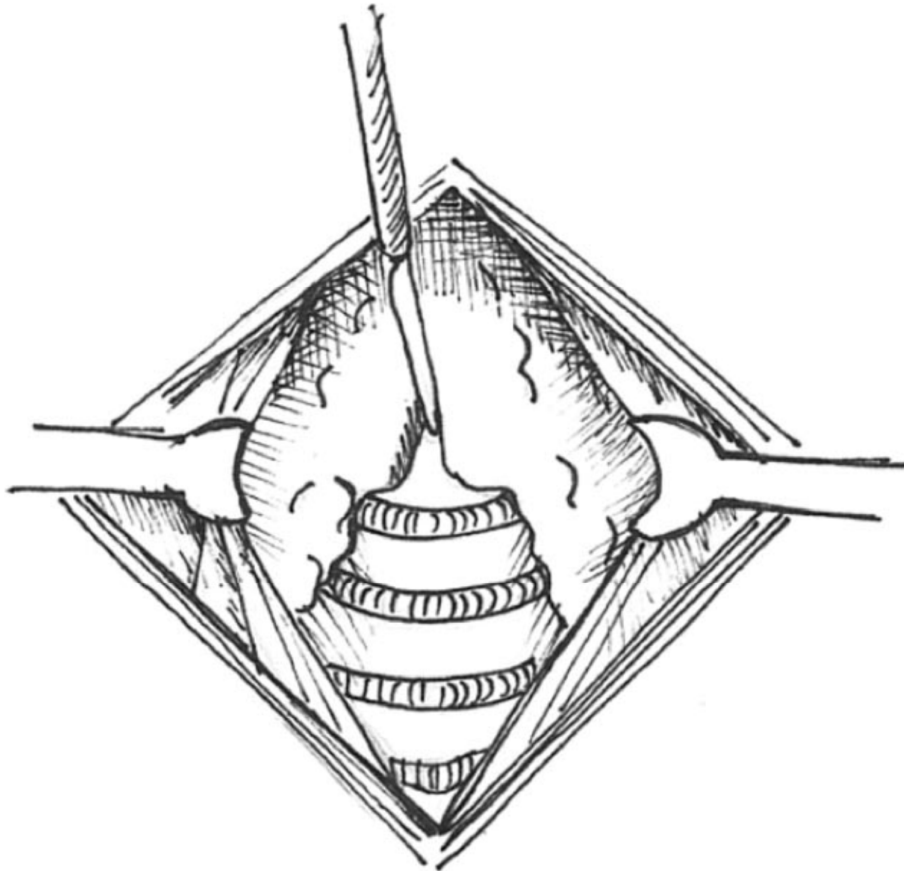


Fig 9 courtesy-international article Tracheostomy: Why, When, and How?

It will be better to identify the cricoid cartilage and so it will be useful to us as to decide the point of entry into the windpipe. Ideally, trachea should be entered between the second and fourth tracheal rings.

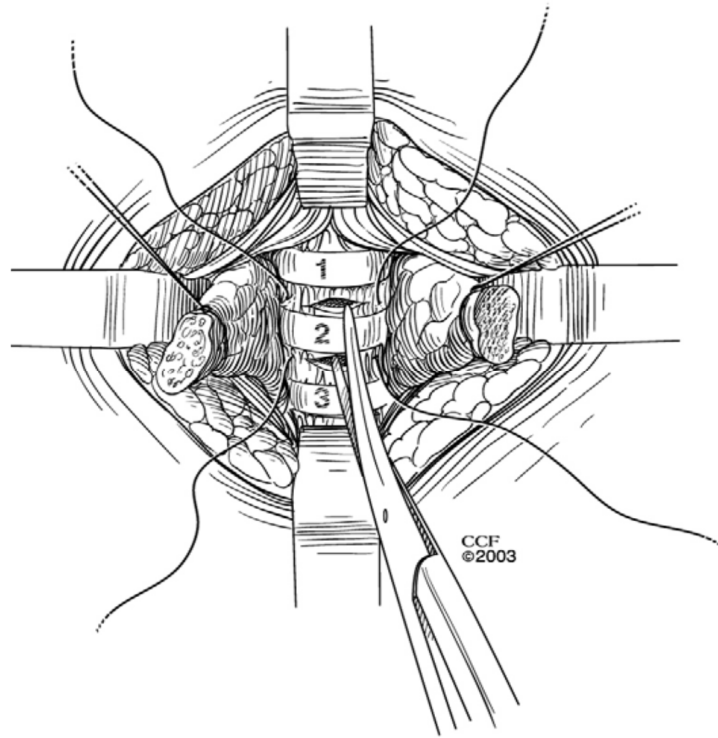


Fig 10 courtesy-clinics in chest medicine Techniques of surgical tracheostomy

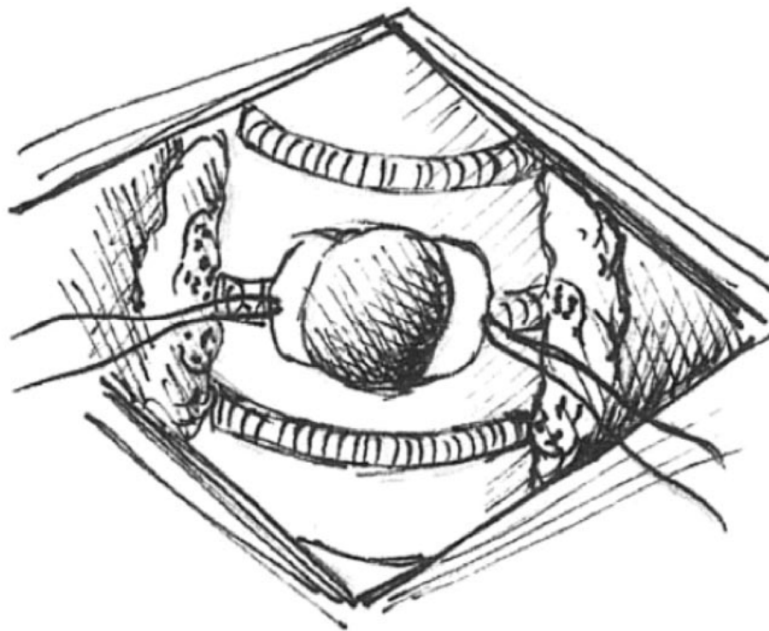


Fig 11 : courtesy-international article Tracheostomy: Why, When, and How?

Another technique to enter into trachea is by creating a Bjork flap ,trap door in which small part of tracheal cartilage is pulled down and suture to skin. This helps in easy reinsertion of tracheostomy tube if accidentally extubated in patients with altered anatomy or obesity. Before placing the tracheostomy tube the size and cuff of tracheostomy tube should be cross checked and all the connecting equipment works properly, so that once connected to ventilator, mechanical ventilation can continue without any hindrance. The anaesthetist should be informed prior to tracheotomy.

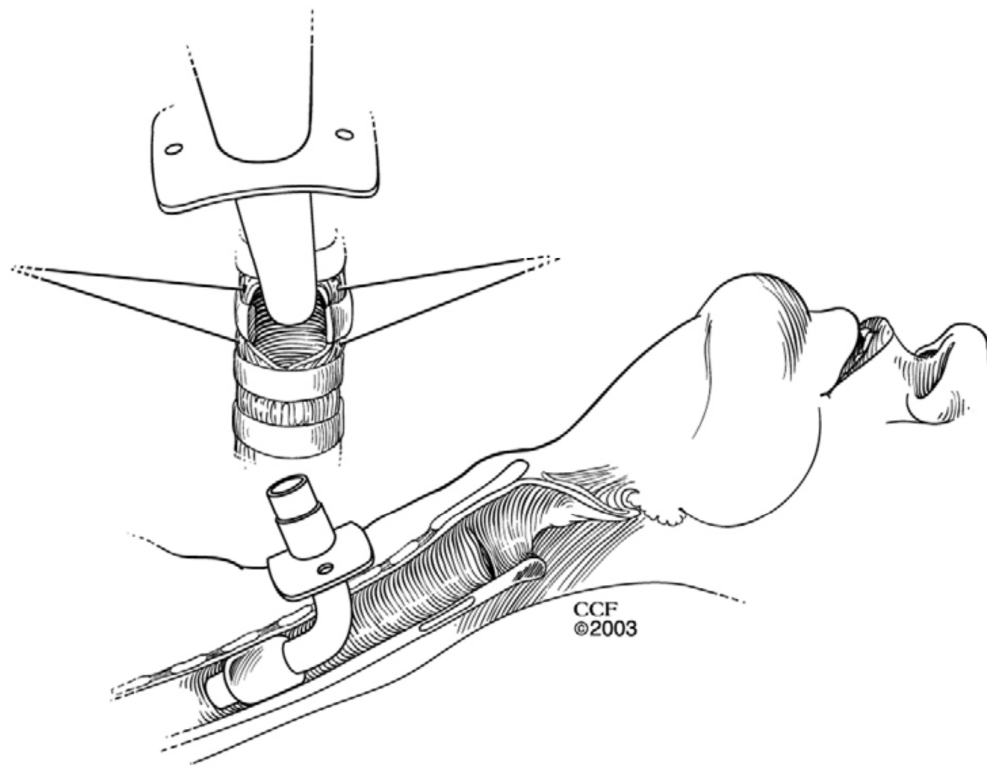


Fig 12 courtesy-clinics in chest medicine Techniques of surgical tracheostomy

Once the trachea has been entered surgeon should direct the anaesthetist to withdraw the translaryngeal tube while visualising the tube being withdrawn then the surgeon can ask the anaesthetist to stop the withdrawal once the endotracheal tube is immediately above the tracheostomy. Then the portex cuffed tracheostomy tube should be inserted. The cuff should be inflated and the tracheostomy tube connected to the ventilation circuit. The incised layers should be closed loosely. The tracheostomy tube secured in proper position with tapes and stay sutures.



Fig 13 Examples of available appliances: (A) Bivona TTS, Bivona Medical Technologies, Gary, IN. Note the deflated cuff is flush with the tracheostomy tube (tight to shaft). (B) Flexible wire-reinforced, adjustable-length tube, Willy-Rusch AG, Kernen, Germany. The mobile flange is not included in the picture. (C) Fenestrated Shiley, Mallinckrodt Inc., St. Louis, MO. Passage of air through the fenestration allows for phonation with the tube capped. (D) Shiley XLT, proximal extension. Note the extended length of the proximal portion from elbow to flange. (Taken from Techniques of surgical tracheostomy).

CHOICE OF THE TUBE¹

The choice of tracheostomy tube depends on several factors like the postoperative needs of the patient, his/her anatomy of neck, patient comfort and effective management of the tracheostomy.

It is advised to choose an tracheostomy tube with inner tube so that it can be removed and cleaned. It has been established that the tracheostomy tube can remain in place for up to 29 days without interfering the airway. The cuffed tracheostomy tube should be the first tube to be inserted at the time of surgery. The most commonly used tubes are polyvinylchloride (PVC) tubes. These tubes are available with or without cuffs and fenestrations. A tracheostomy tube corresponding to the size of patient's windpipe should be inserted. Too small tube will increase airway resistance, thereby increasing the work of breathing on spontaneous respiration. Moreover cuff pressures should be increased to create a tight seal around the tube to prevent aspiration. This in turn will damage the laryngeal mucosa. If the tube is large, it will be difficult to insert and can result in insufficient leakage past the cuff while weaning the patient. Minitracheostomy tubes are smaller with 4mm inner diameter inserted through the cricothyroid membrane. It allows size 10 suction catheter to pass through. It cannot be used in patients with inadequate airway reflexes as it is uncuffed and its diameter does not fit for mechanical ventilation.

CUFF

Cuffs in a tracheostomy tube provides an airtight seal to prevent aspiration of secretions or positive pressure ventilation. The pressure of air within the cuff must be monitored with a cuff monitor high enough to ensure an adequate seal, but not too high as to damage the laryngotracheal mucosa which eventually leads to subglottic stenosis. The use of high volume, low pressure cuffs have helped to reduce this unwanted problem by maintaining a cuff pressure of 15–25cmH₂O.

INNER TUBE

Now several tubes are available commercially with an inner tube. The tip of the inner tube projects a few millimetres beyond the distal end of the outer tube¹. This inner tube will prevent the secretions from blocking the outer tube. Thus the inner tube can be removed and cleaned while maintaining the patency of the airway.

FENESTRATION

In a tracheostomy tube fenestration is made at the point of maximum curvature in the form of a single hole or a number of small holes. Through which air passes from the tube through the larynx so promoting air available for phonation and increasing the voice quality. These tubes have an inner tube which is fenestrated as well as tubes that are not fenestrated, meeting the clinical needs of the patient without affecting the airway.

FLEXIBILITY¹

In some patients a rigid tube will not conform to the anatomy , so that it keeps rubbing against the tracheal wall or end up lying at an awkward angle. These circumstances are overcome by using a softer flexible tube made of silicone. Even if the softer tube gets kinked resulting in obstruction then an armoured flexible tube can be used. Armoured tubes are those tubes which are reinforced with metal wire along the shaft of the tube which needs to be considered while doing imaging or while patient is undergoing radiotherapy.

ADJUSTABLE FLANGE¹

The intratracheal length of the tube can be altered with an adjustable flange when the depth of the stoma increases. This could be due to alterations in anatomy because of a huge thyroid swelling or to bypass any upper airway intraluminal obstruction.

These tubes come without an inner tube so they can be easily blocked requiring tube change after 7-10 days. The Uniperc TM¹ adjustable flange tracheostomy tube (Portex) has been devised for patients with larger neck and it can be inserted surgically or percutaneously. This has an inner tube which may be removed, cleaned and replaced, hence it may stay in place for 29 days. It is not advisable to send patients home with single lumen tubes. The Moores tube (Kapitexs) is flexible, possesses an inner tube system and comes into practical use when a long, soft, flexible tube is needed and when the cuff is not needed.

Flexible and adjustable flange tubes can be customized according to patient's needs.

POSTOPERATIVE CONSIDERATIONS

On their return to the ward, it is important that the patient is looked after by a nurse who is experienced in the care of tracheostomy patients and knowledgeable about the potential complications, as well as the different types of tubes. Local guidelines, procedures or protocols should be in place for the management of patients with a tracheostomy. Communication materials must be available for the patient. The portex tracheostomy tube inserted during the procedure must be secured in position for at least 3-5 days. This is necessary for a good tract to form. This tube may be changed into a metallic tracheostomy tube after 7 days, if this is clinically warranted, and any sutures applied during surgery can then be removed. Tubes should be kept secured with tapes around the neck by a secure knot with neck in a neutral position. If the neck is not maintained in neutral position when the tapes are secured, then the tapes will be too lengthy and will not secure the tube in the appropriate position. This can cause accidental extubation when patient coughs violently. These cuffed tubes are kept inflated until the risk of aspiration is present and in most cases cuff can be deflated after first 12 hours.

Following tracheostomy, the air being inspired passes directly into the trachea. Process of warming and humidification done by nasal passage is bypassed. This leads to irritant air reaching the trachea and increasing the quantity

and viscosity of tracheal secretions. Thus patient may need adequate suctioning in the immediate postop period .humidified oxygen, nebulizers or heat and moisture exchangers is necessary to decrease the risk of tube obstruction due to crust formed by drying up of secretions. Over time, patient realizes that secretions can be cleared by coughing out, thus need for suctioning reduces.

Swallowing problems are quite common following tracheostomy. These are usually due to the sensation of pressure in the upper oesophagus because of an inflated cuff .also during swallowing, movement of larynx is reduced because of a tethering effect of the tube.

If at any stage there are doubts regarding the position of the tube, or whether the lumen of the tube is obstructed, a flexible nasal endoscope can usually be passed through the tube to inspect the lumen of the tube and the trachea

COMPLICATIONS

IMMEDIATE

The most common and most fatal complication of tracheostomy is hemorrhage. It is usually due to damage to the thyroid veins or the thyroid isthmus.by the end of the surgery if the bleeding still continues then re exploration of wound is necessary and the ligation of bleeding vessel should be done.

Next is air embolism, it occurs when air is sucked into large veins due to accidental injury to large veins. Its a life threatening situation. Damage to the contents of the carotid sheath, oesophagus or recurrent laryngeal nerve occurs due

to altered anatomy .in the hands of inexperienced surgeons ,chances of damage is high as they deviate away from the midline. The apex of the lung may extend into the lower neck in emphysematous patients and can get injured during lateral dissection. An adequate incision, good retraction or complete haemostasis can result in ideal exposure and consequent damage to the tracheal walls or cricoid cartilage is less likely to occur. Injury to cricoid cartilage should be addressed at the time of surgery itself. Thus Immediate complications are less likely if good haemostasis is achieved during surgery and by proper surgical technique.

INTERMEDIATE

Accidental extubation can occur if the tube is not properly secured by suturing the flanges of the tracheostomy tube to the skin. Tube displacement can occur and comes to lie in pretracheal space .Gradually soft tissues around the tube can prolapse around the tracheal window and seal it. Initially patient may not complain of breathing difficulty but eventually he will land up in dyspnoea once the tracheal opening is completely closed. Thus a flexible scope in this situation passed through the lumen of the tube can identify displacement or obstruction of the tube. It could be due to crusting, granulation tissue or improper placement of the tracheostomy tube tip, which thereby irritates the tracheal mucosa subcutaneous emphysema can occur if the tube or the trachea is obstructed or tight closure of skin incision ,which causes air to leak into the soft tissues of the neck. Under these circumstances, air can ascend up to the lower eyelids and down into the upper chest. In severe cases, the swelling may even cause tube displacement. Tracheo-oesophageal fistulae can occur due to intraoperative damage to the

posterior wall of the windpipe or persistent rubbing of the tip of the tracheostomy tube on the posterior wall of the trachea and thereby causing mucosal injury in the early postoperative period. These patients present with signs of aspiration though the cuff is inflated.

Tracheoarterial fistulae is commonly seen in previously irradiated patients, especially if low tracheostomy is carried out. There is no warning sign and suddenly they present with a bout of explosive haemorrhage. Innominate artery is the most common artery to be affected. Immediately the tube should be changed into cuffed one and inflated to prevent further aspiration of blood and compress the bleeding vessel via the tracheostoma. Immediate exploration of wound is mandatory.

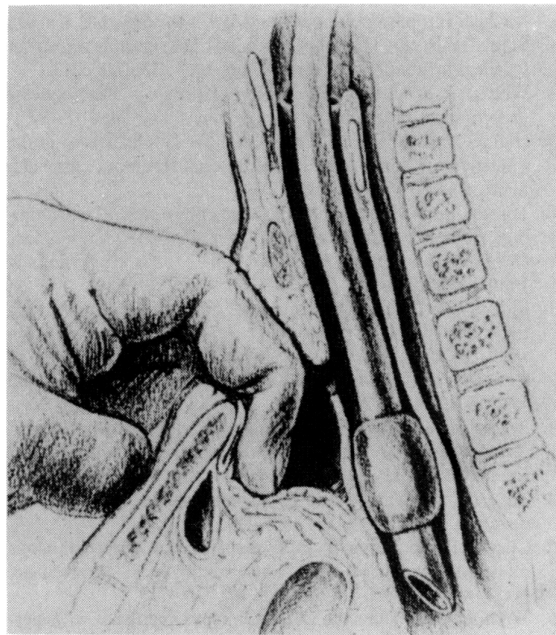


Fig-14 courtesy- Illustration showing digital compression technique for emergency control of massive haemorrhage due to tracheo-innominate artery fistula. Reproduced with permission from JAMA 220(4), p. 578. Copyright 1972, American Medical Association.

Epithelialization of the tracheostomy tract normally occurs in the evolution of a tracheostomy. The tract persists longer if the tracheostomy has been present for a longer time. The longer the tracheostomy has been present, the more established the process is and the more likely the tract is to persist following decannulation. If an airtight seal is maintained after the stoma being occluded, it can be greatly avoided.

Presence of granulation tissue in the fistula can be treated with simple cautery with silver nitrate. Few cases will require surgical closure. This is done by excising the tract down to the tracheal wall and closing it in several layers. Tracheal stenosis occurs as the result of damage to cricoid cartilage or of the first tracheal ring at the time of surgery. It can also be damaged by the rubbing of a poorly positioned tube, resulting in mucosal inflammation.

Decannulation

First the initial cuffed tube should be replaced by a uncuffed tube. Then downsize the tube. This is not needed if the patient is able to breathe around the tube. The tube should be kept blocked during the day and then unblocked at night for the first 24 hours. If the patient is able to tolerate this, then the tube can be kept occluded for next full 24-hour period. Some patients may find it difficult to get through the decannulation process as they are worried of being unable to breathe without the tube. After removal of tracheostomy tube an airtight dressing is to be applied. Patients should be advised to support the tracheostomy dressing site while coughing and talking.

Review of Literature

REVIEW OF LITERATURE

Stauffer et al in 1981 reported 66% complication rate in patients with tracheostomy in contrast to usual 5-6% which was prevalent at that time.

Whited et al in 1984 in his prospective study found that patients intubated less than 5 days had no long term complications whereas patients intubated longer than 11 days had 12% incidence of chronic stenosis

Colice et al in 1989 found 19% incidence of post intubation laryngeal injuries such as hoarseness, dislocation of arytenoids, vocal cord palsy and glottis incompetence in his study.

Rodriguez et al. in 1990 studied 106 mechanically ventilated trauma patients in a prospective randomized controlled study. They randomized 51 patients to early tracheostomy (within 7 days of intubation) and 55 patients to late tracheostomy (> 7 days). They were able to demonstrate a significant decrease in the duration of mechanical ventilation, and ICU and length of hospital stay in patients randomized to early tracheostomy.

Lanza et al. in 1990 retrospectively reviewed head injury patients to examine the predictive value of the GCS for tracheostomy in these patients. Of 47 patients divided according to their GCS rating, 34 had a $GCS \leq 7$ and 13 had $GCS > 7$. They found that the likelihood of tracheostomy is significantly greater in patients with $GCS \leq 7$.

Lesnik and coworkers in 1992 retrospectively studied 101 patients with blunt multiple trauma of which 32 were tracheostomized within 4 days of intubation. Early tracheostomy resulted in reduction of mechanical ventilation duration as well as in the incidence of nosocomial pneumonia

D'Amelio et al. in 1994 studied 43 trauma patients retrospectively, tracheostomy was done in 31 patients. Patients who had tracheostomy done within the first 7 days of intubation had lower mechanical ventilation duration as well as ICU and hospital length of stay.

Ross and colleagues in 1996 examined the various factors to predict the need for prolonged ventilatory support in trauma patients. A total of 212 trauma patients were studied. They concluded that age more than 40 years, GCS less than 7 and alveolar-arterial oxygen gradient ($A-a O_2$) ≥ 100 to 150 were predictors of prolonged mechanical ventilation

Velmahos and coworkers in 1997 reviewed 125 patients who required mechanical ventilation for > 48 hours. In this study, prolonged mechanical ventilation was defined as the need for mechanical ventilatory support for > 7 days. The use of a Swan Ganz catheter, injury severity score, PaO_2/FiO_2 ratio at 48 hours, and positive fluid balance at 48 hours were most predictive of prolonged mechanical ventilation.

Koh et al. in 1997 conducted a retrospective study on 49 patients, 20 of which were victims of trauma, who required admission to the neurosurgical ICU.

In this study, the reintubation rate was 22% despite meeting weaning criteria. Among the predictors of failed extubation were low Glasgow Coma Scale (GCS) and excessive tracheal secretions

Sugerman et al in 1997 found no difference between ET and LT group in the incidence of pneumonia.

Armstrong and colleagues in 1998 performed a retrospective chart review of 157 blunt trauma patients who were divided into an early tracheostomy group (less than 6 days of intubation, n = 62) and late tracheostomy group (> 6 days, n = 95). They found that early tracheostomy was associated with a shortened ICU and hospital length of stay.

Chia-Lin Hsu and his colleagues did a retrospective study of 163 patient in July 1998 –June 2001. 93 male and 70 female; mean age 70 years, range 19–104 years; The indications for intubation in the 163 patients were categorised into: pulmonary (n = 107), infectious (n = 18), neurological (n = 28) and circulatory (n = 10) disease.. The mean number of days of intubation was 18.5 ± 10.9 days (range 1–62 days). The most common early complication of tracheostomy was bleeding (moderate amount in 11 [6.7%] and minor bleeding in 46 [28.2%]), followed by subcutaneous emphysema (3 [1.8%]; In two this occurred along with bleeding and in one it occurred with air leakage) and obstruction (3 [1.8%]). The most common late complication was bleeding in 4 patients [2.5%]), followed by air leakage (3 [1.8%]) and tracheal stenosis in 2 patients [1.2%]). The patients who underwent early tracheostomy also had shorter post-tracheostomy ICU stays

(10.8 versus 14.2 days) and weaning periods (19.0 versus 44.3 days, $P < 0.001$). . The early tracheostomy patient group had a greater rate of successful weaning (56.4% versus 30.2%, $P = 0.002$) and lower ICU mortality (14.5% versus 28.3%, $P = 0.05$), but there were no differences between early and late tracheostomy groups in terms of hospital mortality

Gurkin et al. in 2002 examined the factors that can predict tracheostomy in patients with traumatic brain injury. All traumatic brain injury patients who required intubation and lived longer than 7 days were included; 246 patients with head injury were identified, of whom 35 required tracheostomy. They found that a $GCS \leq 8$ on admission and Injury Severity Score ≥ 25 are highly predictive of tracheostomy.

Bouderka et al in 2004 studied reduced duration of mechanical ventilation, shorten ICU stay and hospital stay .Also studied no difference in pneumonia between ET and continued intubation(58vs61%),delay in pneumonia occurrence(6.7 ± 1.8 vs 9.2 ± 2.3) and faster recovery from ventilator dependence (6 ± 4.7 vs 11.7 ± 6.7)

Rumbak et al in 2004 -did a prospective study in 120 patients comparing early versus late tracheostomy. He found reduced time of mechanical ventilation in early tracheostomy group (<48 hrs) 7.6 ± 4.0 vs 17.4 ± 5.3 days (late tracheostomy group >48 hours).He also found reduced length of stay in intensive care patients after early tracheostomy(4.8 ± 1.4 versus 16.2 ± 3.8 days)he also studied

50% reduction in mortality rate after ET (19 vs 37%) and also concluded more patients died of ventilator associated pneumonia in LT more than ET (9 vs 2).

Flatten et al did a study on 461 patients retrospectively and found reduced median number of days on ventilator after ET (4.7 vs 14.7 days). He also studied decreased length of stay in ICU patients after early tracheostomy (<7 days) compared with LT (6.8 vs 12.7 days).

Arabi et al in 2004 also confirmed ET better than LT with respect to length of stay (10.9 ± 1.2 vs 21.0 ± 1.3 days) and also found no difference in overall hospital length of stay. He neither found a difference in ICU patients (3 vs 1%) nor in overall hospital mortality (17 vs 14%) between two groups of ET and LT.

Moller et al in 2005 compared ICU patients before and after tracheostomy. He found reduced ICU length of stay (16.7 ± 1.0 vs 26 ± 1.3 days) as well as shortened hospital stay (22.8 ± 1.2 vs 33.4 ± 1.7 days) in patients whom had early tracheostomy. He also found decrease in VAP after ET (27 vs 72%).

Boubaker Charra et al in 2009 showed a significant statistical decrease of the whole duration of mechanical ventilation for the Tracheostomy Group: 27.03 ± 3.31 days versus 31.63 ± 6.05 days for the Intubation Group ($P = 0.001$). A total of 60 patients, who required mechanical ventilation, were recruited in our study. The mean age was 41 ± 11 years. The mean duration of hospital stay didn't differ between the two groups; it was 30.96 ± 9.47 days for the tracheostomy group versus 34.26 ± 9.74 days for the intubation group ($P = 0.10$). With respect to

mortality between the two groups it shows that there is no statistically significant difference 26.7% in the tracheostomy group versus 46.7% for the intubation group ($P = 0.10$). Moreover there was no difference in mortality in the ICU (26.7 % vs. 46.7 %; $p = 0.1$) and in the duration of stay in ICU (30.96 ± 9.47 vs. 34.26 ± 9.74 ; $p = 0.2$) between both groups.

Tareq Mahafza et al in 2012 included a total of 106 patients, who were subjected to an elective surgical tracheostomy because of prolonged intubation and failed extubation or/and weaning. Out of these 106 cases, there were 74 (70%) males and 32 (30%) females, and their age ranged from 2 months to 90 yr with a mean age of 46.5 yr.. Early tracheostomy (within 3 weeks of an ICU admission) was done in 70 (66%) patients while 26 (24.5%) patients had the tracheostomy done in the 4th week, 6 patients had tracheostomy (5.7%) done in the 5th week, 3 (2.8%) cases done in the 6th week, and 1 (.9%) case of tracheostomy was done in the 7th week of tracheal intubation. The length of stay in the ICU for these patients was 41 days, ranged from 3 to 28 weeks (26:47 days early to late tracheostomy ratio), and the overall mortality rate was 26 (24.5%), significantly higher death rate 13 (36.1%) among late tracheostomy than early tracheostomy 17.1%.] The rate of ventilator-associated pneumonia among our patients was 33, more common with patients who had late tracheostomy (41.7%) than with early tracheostomy patients (28.6%) .Regarding airway injuries, we have found that 12 (33.3%) of our patients who had late tracheostomy did develop airway injuries while 16 (22.9%) of patients with early tracheostomy had airway injuries.

In a retrospective analysis by Bickenbach et al, early tracheostomy was found to reduce the duration of artificial ventilation as well as ICU length of stay.

Sanabria et al in 2013 studied 163 patients of which (62%) were male, and the median age was 59 ± 17 years. Almost one-third (36%) of patients required mechanical ventilation longer than 7 days and 16% of patients were extubated after day 8 of intubation.

Suzuki and Kusunoki et al study in 2013 surveyed 100 patients needing tracheostomy in the Critical Care Medical Center of Hiroshima. The researchers set their definition of ET as <10 days after intubation and LT as >10 days after tracheal intubation. Comparing data between ET (49 patients) and LT (51 patients) groups, they concluded that ET shortened the length of weaning after tracheostomy but found no difference in the length of ICU stay and clinical outcome.

Andriola et al in 2015 included 1977 patients in a meta analysis, divided them into ET (less than 10 days after tracheal intubation) and late tracheostomy group (more than 10 days after intubation). They found out that early tracheostomy had lesser risk of mortality at the longest follow-up time available in seven studies that measured mortality (ranging from 28 days to two years of follow-up), as compared with patients who underwent a late tracheostomy. They also found out that no significant differences for pneumonia occur between two groups.

Meng 1 and his colleagues in 2016 did a systematic review and meta analysis and found that in a total 2040 patients, 1018 had early tracheostomy while 1022 had late tracheostomy. ET might be able to reduce the duration of sedation but did not significantly alter the mortality, incidence of VAP, duration of MV and length of ICU stay.

Aims & Objectives

AIMS AND OBJECTIVES

1. To compare prolonged endotracheal intubation with tracheostomy in toxicology ICU patients requiring prolonged mechanical ventilation.
2. To study the complications associated with tracheostomy and endotracheal intubation.
3. To define optimum time to carry out elective tracheostomy

Materials & Methods

MATERIALS & METHODS

STUDY PLACE : Rajiv Gandhi Govt General Hospital, Chennai-600003

COLLABORATING DEPARTMENT :

Upgraded Institute of Otorhinolaryngology and Department of Internal Medicine

STUDY DESIGN : Retrospective and Prospective Comparative study

STUDY PERIOD : May 2016 – October 2017

SUBJECT SELECTION:

Toxicology intensive care unit patients and patients coming to UIORL , MMC, RGGGH

INCLUSION CRITERIA:

1. Age above 15 years
2. Both sexes (male and female)
3. Requiring prolonged mechanical ventilation

EXCLUSION CRITERIA:

1. Age less than 15 years
2. Laryngotracheal trauma
3. Malignant growth larynx

ETHICAL COMMITTEE APPROVAL

Institutional Ethical Committee, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai reviewed the experimental design and protocol as well as the letter of information and consent form. Full approval of the board was granted. All patients were given information outlining the experimental protocol and all the patients signed a consent form prior to entering the study.

METHODOLOGY

It is a retrospective and prospective comparative study of 100 intensive care unit patients requiring prolonged mechanical ventilation.. After getting approval from the ethical committee, this study was conducted .it was carried out in our tertiary care hospital affiliated to a teaching Institute. The period of the study is from May 2016 to Oct 2017.

The total number of patients included in our study are 100, between the age group of 15-75 years of both sexes. These patients are intubated as their Glasgow Coma Scale (GCS) falls less than 8. This scale was introduced with the aim of assessing the level of neurological injury .It comprises of following components assessment namely movement, speech and eye opening. brain injury is categorised as severe(if GCS less than 8),moderate(9-12) and mild if GCS more than or equal to 13 .This assessment should be done immediately to evaluate whether patient can maintain airway on his own and also to determine the prognosis.

GLASGOW COMA SCALE

Best eye response (E)	Spontaneous--open with blinking at baseline	4
	Opens to verbal command, speech, or shout	3
	Opens to pain, not applied to face	2
	None	1
Best verbal response (V)	Oriented	5
	Confused conversation, but able to answer questions	4
	In appropriate responses, words discernible	3
	Incomprehensible speech	2
	None	1
Best motor response (M)	Obeys commands for movement	6
	Purposeful movement to painful stimulus	5
	Withdraws from pain	4
	Abnormal (spastic) flexion, decorticate posture	3
	Extensor (rigid) response, decerebrate posture	2
	None	1

Table Courtesy-intechopen.com

Then spontaneous breathing trial(SBT) attempted on the third day. SBT is the ability of the individual to sustain spontaneous breathing that is extubation readiness. This is determined by patient's respiratory pattern, amount of gas exchange, haemodynamic stability and comfort of the patient. He /she is considered fit if they can tolerate SBT for 30-120 minutes. Failed SBT is determined by the following parameters.

Signs of intolerance to spontaneous breathing (weaning failure)
$\text{PaO}_2 < 50\text{-}60 \text{ mmHg}$ and $\text{FiO}_2 > 0.5$
$\text{SaO}_2 < 88\text{-}90\%$ and $\text{FiO}_2 > 0.5$
$\text{PaCO}_2 > 50 \text{ mmHg}$ or increased by more than 8 mmHg
$\text{pH} < 7.32$ or reduced by more than 0.07
$\text{RR} > 35 \text{ breaths/min}$ or increased by more than 50%
$\text{HR} > 140 \text{ bpm}$ or increased by more than 20%
$\text{SBP} > 180 \text{ mmHg}$ or $< 90 \text{ mmHg}$
Uncontrollable psychomotor agitation
Reduced level of consciousness
Excessive sweating and cyanosis
Evidence of increased respiratory muscle effort

Courtesy-boles et al 5d

Few patients have undergone reintubation due to increased upper airway resistance, poor cough, excessive secretions, poor airway reflexes leading to aspiration, respiratory weakness masked by pressure support and onset of any new pathology. If SBT fails, then intubation is either continued or tracheostomy is planned. we have divided tracheostomy patients into two group, one is early tracheostomy (procedure done within one week of intubation) and late tracheostomy (surgery done any time after one week of intubation) according to Griffiths and Barber et al definition. They put forth early tracheostomy (ET) as “as a tracheostomy done up to seven days after admission to the intensive care unit, initiation of translaryngeal intubation, and mechanical ventilation (2005)”. Late tracheostomy (LT) is any time after this. .Tracheostomy is done under local anaesthesia with patient supine and sand bag under shoulders. Local infiltration

given in the Jacksons safety triangle (triangle formed by anterior border of sternocleidomastoid on either side with lower border of cricoid cartilage as the upper limit. Vertical incision is made from lower border of cricoid cartilage to suprasternal notch. Skin, subcutaneous tissue dissected, strap muscles identified and retracted away from midline. Investing layer of deep cervical fascia dissected. Thyroid isthmus identified and retracted from above. Tracheal position confirmed. Then tracheal window created between second and third tracheal rings. Portex tracheostomy tube of low pressure and high volume of appropriate size inserted and bulb inflated. Complete haemostasis achieved. Wound closed in layers. Airway checked and bilateral airway found to be adequate. Perioperative complications are studied which could be ranging from bleeding, sudden desaturation, tube displacement, tube in false track etc., tracheostomised patients are advised the following:

1. To deflate the cuff for 10min once in every hour for first 4 hrs, then every fourth hourly for next 24 hrs after which cuff could be deflated if not contraindicated,
2. Adequate Humidification
3. Frequent suctioning-following are the important steps to be followed while suctioning. It should not be done for more than 30-60 sec. suction catheter diameter equals to or less than one third the inside diameter of tracheostomy tube inserted not more than 15 cm into an adult tracheostomy tube. Suction pressure to be maintained between 8-15 mmhg. when the general condition improves and when the patient meets the following

criteria, patient is weaned from ventilator and decannulation process starts. Those criteria are absence of respiratory distress, stable arterial blood gases, paCO_2 less than 60mmhg, haemodynamic stability, appearance of gag reflex and ability to expectorate. Then date on which weaning from ventilator after tracheostomy is studied. Patients are then transferred to general male or female ward from ICU by which time portex tube is changed to fuller's biflanged metallic tracheostomy tube. Then number of days taken from the date of admission to transfer out is analysed and early tracheostomy group is compared with late tracheostomy group. Mean days taken for tube change between two groups are compared. After which sphigotting is done for full 24 hours, but if patient experiences respiratory distress it can be removed. After successful toleration, wound is strapped for two weeks by which time wound heals. Thus date of decannulation is noted. Average no of days of hospital stay is calculated from date of admission to date of discharge and compared with two study groups. Immediate outcome at the time of discharge also studied these patients are subjected to videolaryngoscopy(VLS) within one month after discharge and it is repeated again after 6 months. Thus the final outcome of patients are assessed at the end of 6 months.

Statistical Analysis & Results

STATISTICAL ANALYSIS

Statistics:

- Data was analysed using SPSS software version 16.0 and P value less than 0.05 was considered statistically significant. Continuous variables were presented as mean \pm SD (standard deviation) and categorical variables were represented as frequencies and percentages.
- Mean was compared by student T test and ANOVA test.
- Categorical variables were analysed by Chi square test.

RESULTS

TABLE-1 : GENDER DISTRIBUTION

GENDER	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
MALE	33	70.21	16	64.00	21	75.00
FEMALE	14	29.79	9	36.00	7	25.00
TOTAL	47	100	25	100	28	100

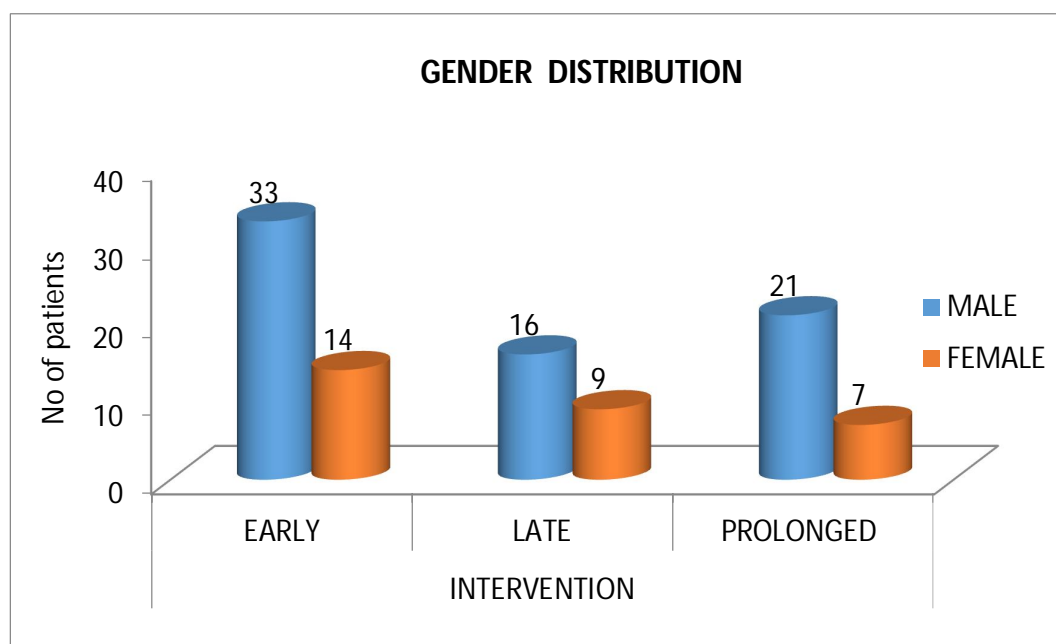
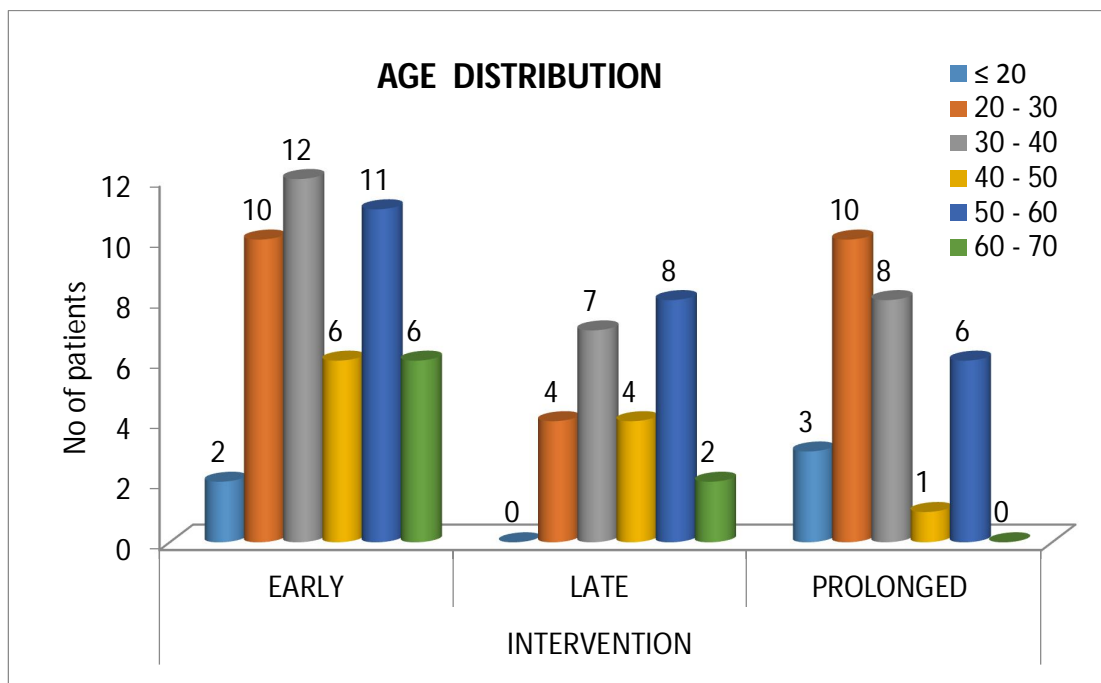


Fig 15 : Bar diagram showing gender distribution

Of the 100 patients, 70 were male and the remaining 30 were female. In early tracheostomy group, males contribute to 70% in comparison to 64% of late tracheostomy group. Females were 29% in early tracheostomy (ET) group when compared to 36% in late tracheostomy (LT). In prolonged intubation group also males are 75% when females were 25%.

TABLE-2 : AGE DISTRIBUTION

AGE GROUP	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
≤ 20	2	4.26	0	0	3	10.71
20 - 30	10	21.28	4	16.00	10	35.72
30 - 40	12	25.52	7	28.00	8	28.57
40 - 50	6	12.77	4	16.00	1	3.57
50 - 60	11	23.40	8	32.00	6	21.43
60 - 70	6	12.77	2	8.00	0	0
TOTAL	47	100	25	100	28	100

**Fig 16 bar diagram showing age distribution**

Of the total study group majority of patients around 26% lie in the age group of 30-40 years followed by 50-60yrs age group. In prolonged intubation group much of the patients around 35% were in age group between 20-30 yrs.in

early tracheostomy group not much of the difference between age groups noted whereas in LT group 32% of patients lie in the age group of 50-60 years.

TABLE-3 : GCS ON DAY 1

	INTERVENTION					
	EARLY		LATE		PROLONGED	
	Mean	Sd	Mean	Sd	Mean	sd
	7.15	1.29	6.88	1.09	6.96	1.04
f-value	0.49					
p-value	0.61					
Significant	Not Significant					

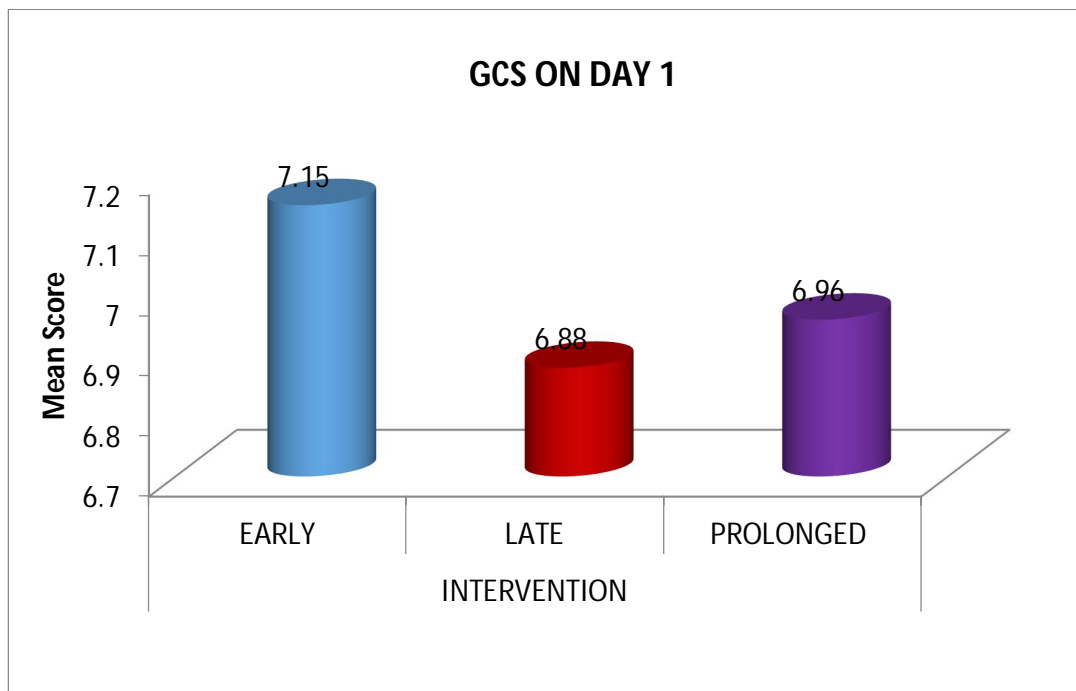


Fig 17 bar diagram showing Glasgow coma scale(GCS)on first day of admission

The mean GCS score of ET group is 7 when compared to 6 of LT group and 6 of prolonged intubation group. p value is 0.61,not significant.

TABLE-4 : GCS ON DAY 3

	INTERVENTION					
	EARLY		LATE		PROLONGED	
	Mean	Sd	Mean	Sd	Mean	sd
	6.48	1.11	6.08	0.81	6.57	2.28
f-value	0.83					
p-value	0.44					
Significant	Not Significant					

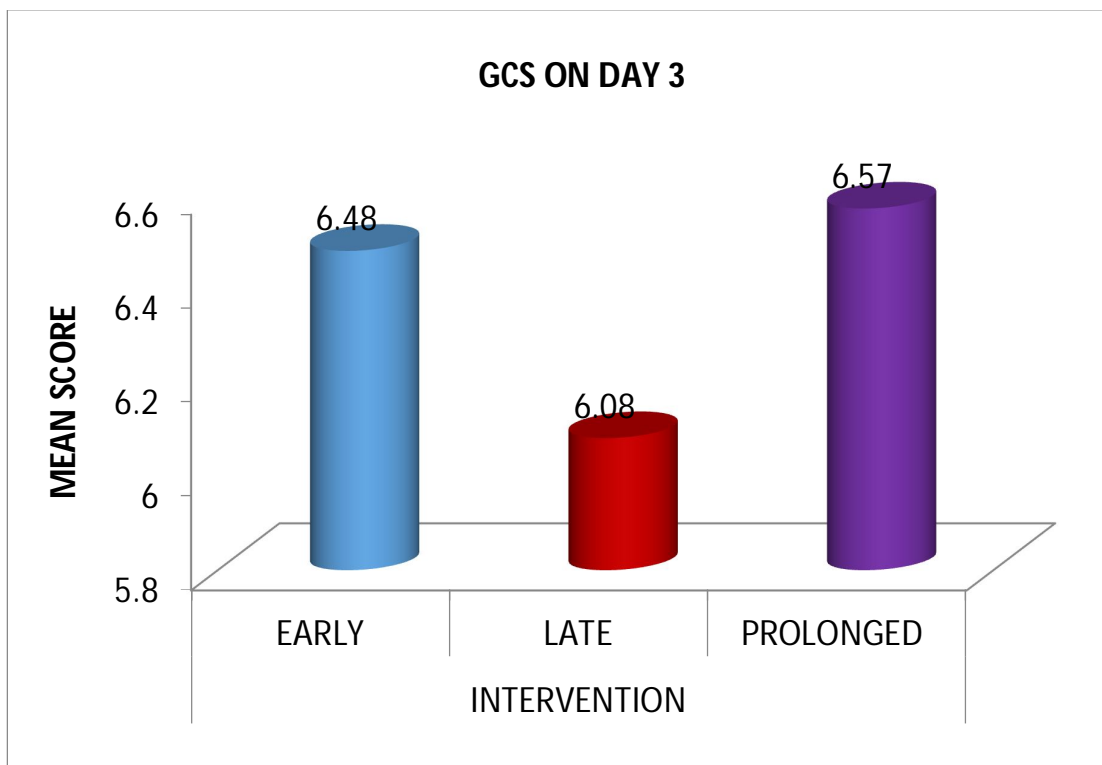


Fig 18 bar diagram showing GCS score on day 3 of intubation

The mean GCS score of all patients were 6, p value is 0.44,found insignificant.

TABLE-5 : REINTUBATION

	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Yes	8	17.02	12	48.00	14	50.00
No	39	82.980	13	52.00	14	50.00
TOTAL	47	100	25	100	28	100
Chi square Value	11.40					
p-value	0.003					
Significant	Significant					

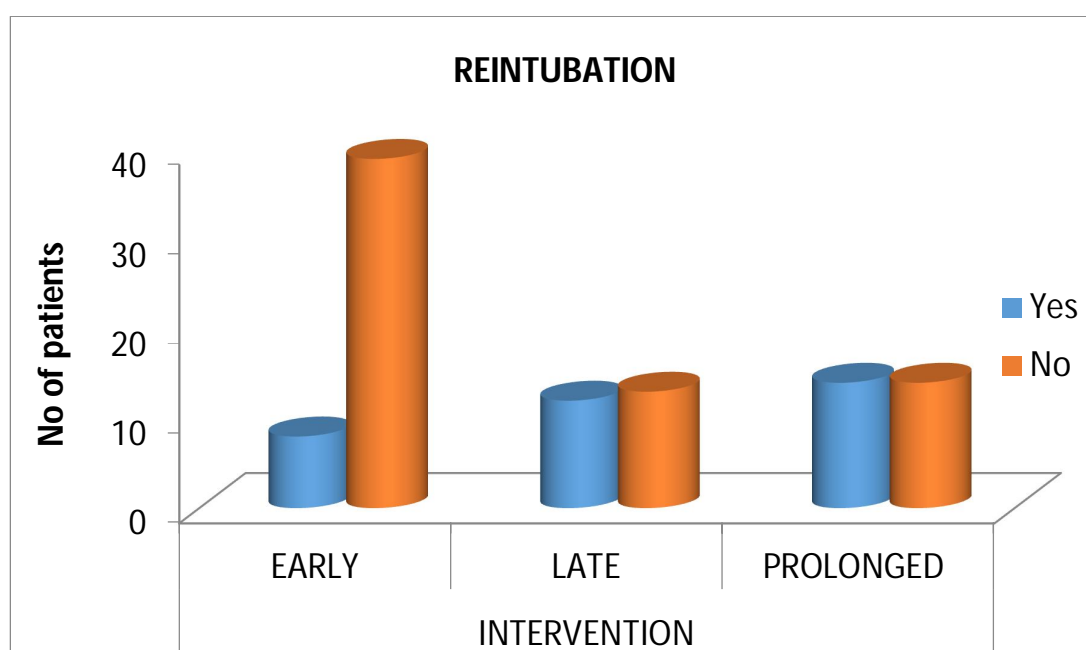


Fig-19, bar diagram showing reintubation attempts in all three groups

Of the total 47 patients of ET group 8 were reintubated which contributes 17%. Among the LT group patients 12 reintubated out of 13 patients contributing around 48%, whereas in prolonged intubation group 14 reintubated out of 14 which contributes to maximum around 50%. p value is 0.003, which is statistically significant. Thus reintubation attempts are more common in prolonged intubation group, followed by LT group, while least common in early tracheostomy.

TABLE-6 : INT CONTINUED /TRACH

	EARLY		LATE	
	N	%	N	%
Continued	0	0	0	0
Tracheostomy Done	47	100	25	100
TOTAL	47	100	25	100
Chi square Value	1.91			
p-value	0.17			
Significant	Not Significant			

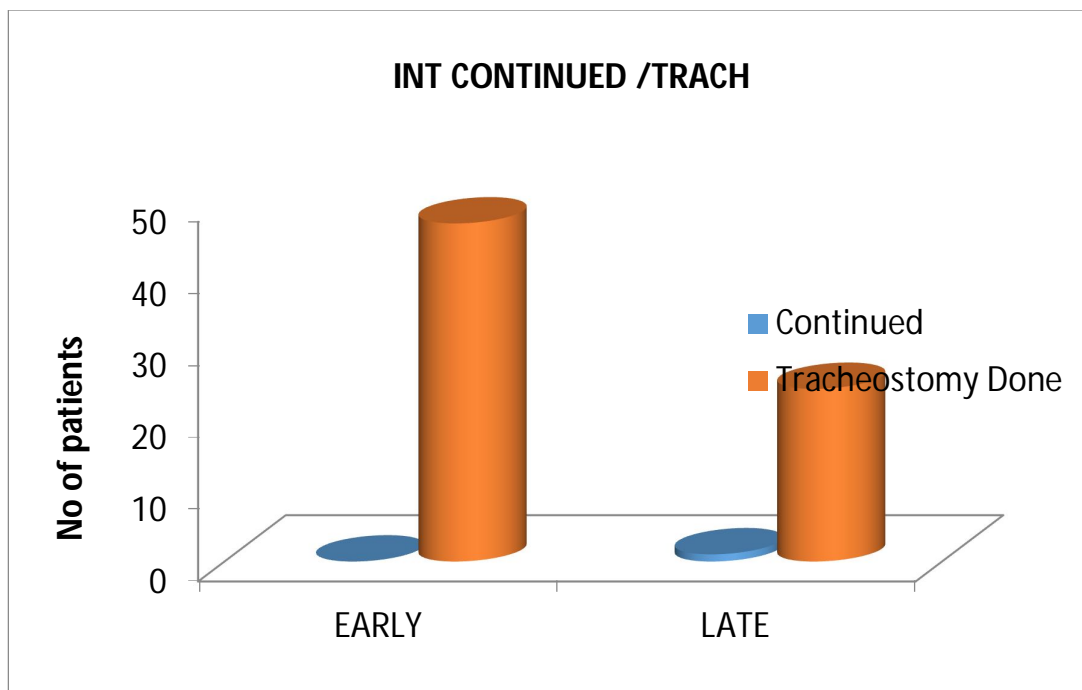


Fig 20bar diagram showing further management of intubated patients.

Of the total 100 patients, tracheostomy was done in 72 patients of which, early tracheostomy(within one week of intubation) was done in 47 patients and late tracheostomy (done anytime after one week) was done in 25 patients .remaining 28 patients continued to be intubated. p value is 0.17,not significant

TABLE-7 : COURSE IN HOSPITAL

	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Denied Tracheostomy	0	0	1	4.00	0	0
Expired	1	2.13	0	0	5	17.86
Improved	0	0	0	0	17	60.71
Poor	1	2.13	1	4.00	0	0
Ventilator Assoc. Pneumonia	0	0	1	4.00	0	0
Hospital Stay	45	95.74	22	88.00	6	21.43
TOTAL	47	100	25	100	28	100
Chi square Value	74.30					
p-value	0.001					
Significant	Significant					

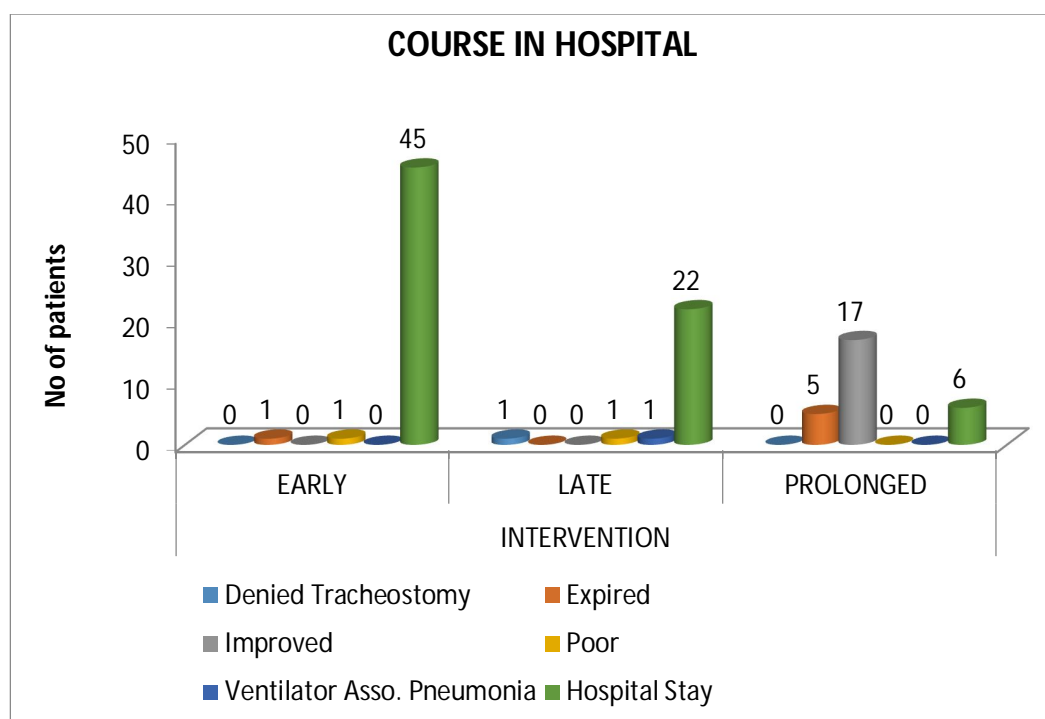


Fig 21 bar diagram showing course of patients while in hospital stay

One patient of LT group denied tracheostomy. one among ET group contributing to 2% and 5 out of prolonged intubation group contributing to 17.86% expired. One patient of late tracheostomy group contributing to 4% developed ventilator associated pneumonia. 17 out of 28 patients of PROL.INT group got improved contributing to 60.71% whereas remaining study patients that is 95.74% of ET group and 88% of LT group had to undergo tracheostomy as their general condition remained the same or got worsened. p value is 0.001, statistically significant.

TABLE-8 : REASON FOR TRACHEOSTOMY

	EARLY		LATE	
	N	%	N	%
Prolonged Ventilation	18	38.30	17	68.00
Tracheo - Bronchial Toileting	11	23.40	4	16.00
Respiratory insufficiency	18	38.30	4	16.00
TOTAL	47	100	25	100
Chi square Value	10.3			
p-value	0.02			
Significant	Significant			

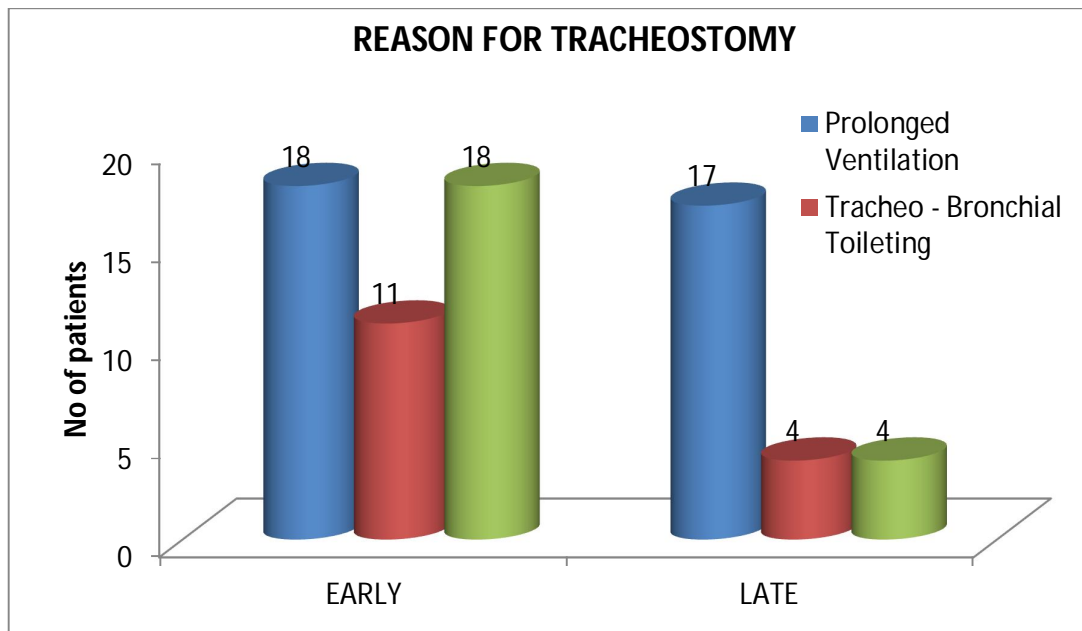


Fig 22 bar diagram showing various reasons for tracheostomy.

Among total 72 patients who underwent tracheostomy, prolonged ventilation remains to be more common cause contributing to 41.6%, followed by respiratory insufficiency contributing to 30.5%. p value is 0.002, significant.

TABLE-9 : INTRA OP COMPLICATIONS

	EARLY		LATE	
	N	%	N	%
Bleeding	1	2.13	0	0
Bleeding from Tracheostomy site	0	0	1	4.00
Tube block	4	8.51	1	4.00
Tube Displacement	1	2.13	2	8.00
Nil	41	87.23	21	84.00
TOTAL	47	100	25	100
Chi square Value	4.26			
p-value	0.37			
Significant	Not Significant			

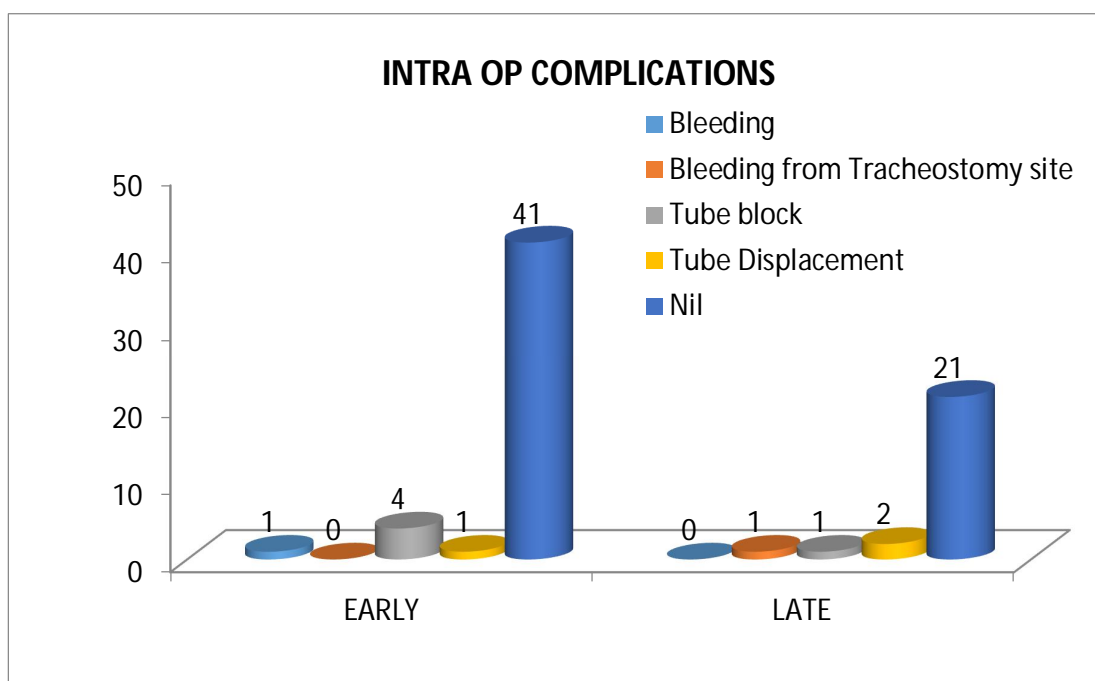


Fig 23,bar diagram depicting intra op complications of tracheostomy

Of the ET group 4 patients had tube block contributing to 8.51% out of 47 patients. 2 out of 25 LT group patients had tube displacement contributing to 8%. 87.23% of ET group and 84% of LT group had no complications intra operatively. Thus p value is 0.37, which is statistically not significant.

TABLE-10 : NEW INTERVENTION

EARLY		LATE		TOTAL	%
N	%	N	%	N	%
47	65.28	25	34.72	72	100

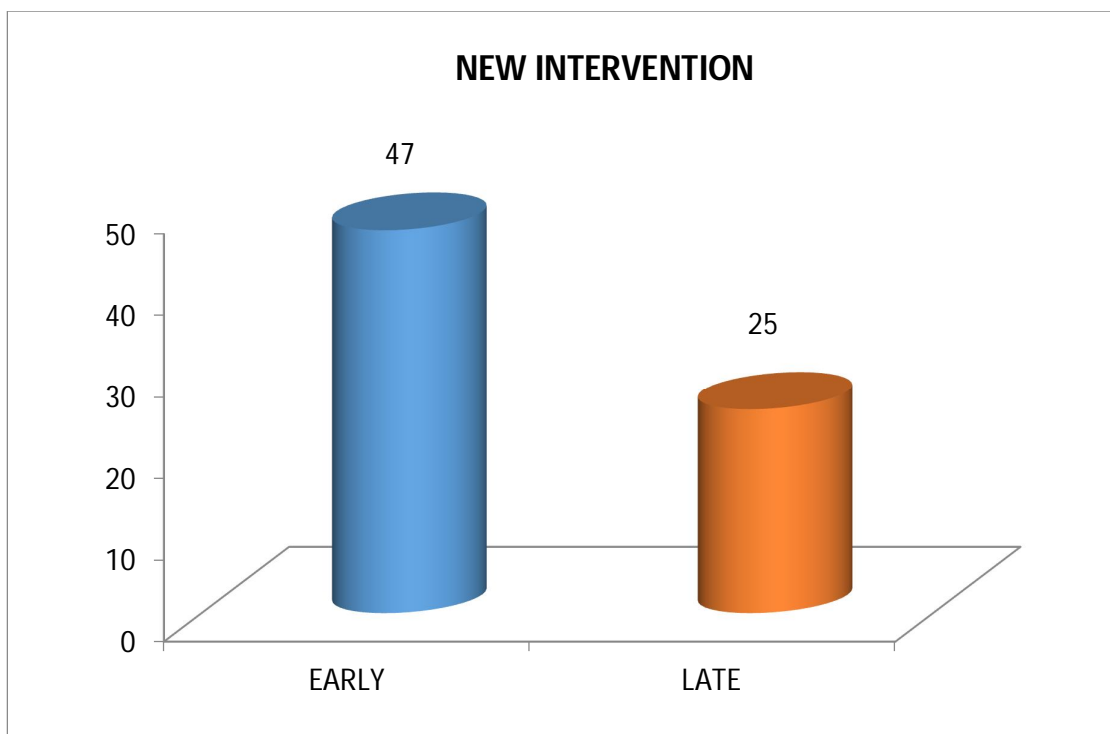


Fig 24 bar diagram showing incidence of tracheostomy

Of the 100 patients, 47 had early tracheostomy contributing to 65.28% while 25 patients had late tracheostomy contributing to 34.72%.

TABLE-11 : IMMEDIATE OUTCOME(AT THE TIME OF DISCHARGE)

OUTCOME	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Complication	0	0	1	4.00	1	3.57
Residual Paralysis	1	2.13	1	4.00	0	0
Improved	42	89.36	18	72.00	21	75.00
Expired	4	8.51	5	20.00	6	21.43
TOTAL	47	100	25	100	28	100
Chi square	6.14					
p-value	0.41					
Significant	Not Significant					

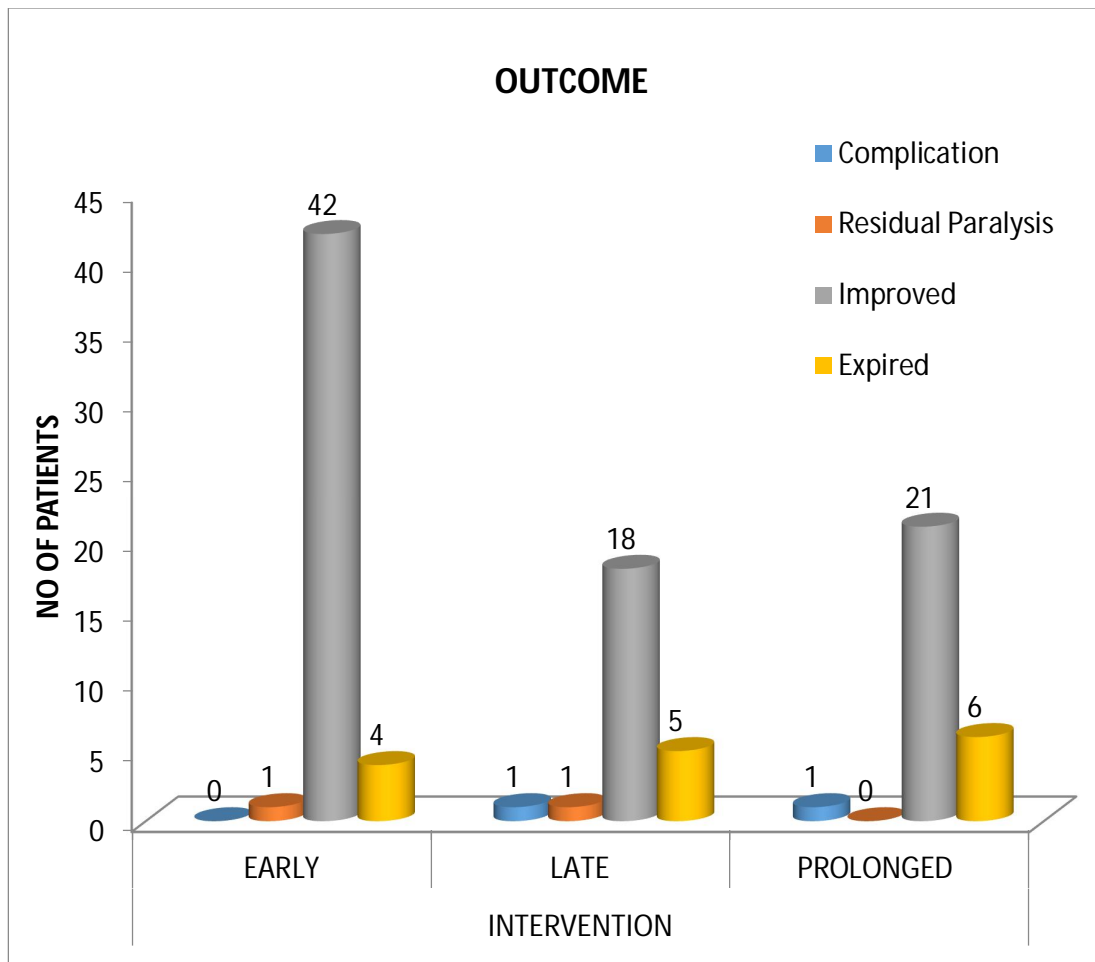


Fig 25 bar diagram depicting the immediate outcome of all the patients at the time of discharge

Among ET group 42 patients improved contributing to 89.36% compared to 72% of LT group .4 among ET and 5 among LT group expired, whereas 6 out of 28 patients of prolonged intubation group contributing to 21.43% died ,one each of ET and LT group had residual paralysis. p value is 0.41, statistically not significant.

TABLE-12

DURATION OF MECHANICAL VENTILATION (IN DAYS)

	INTERVENTION		
	EARLY	LATE	PROLONGED
Mean	10.42	20.86	7.33
sd	4.72	8.30	3.62
f-value	24.93		
p-value	0.001		
Significant	Significant		

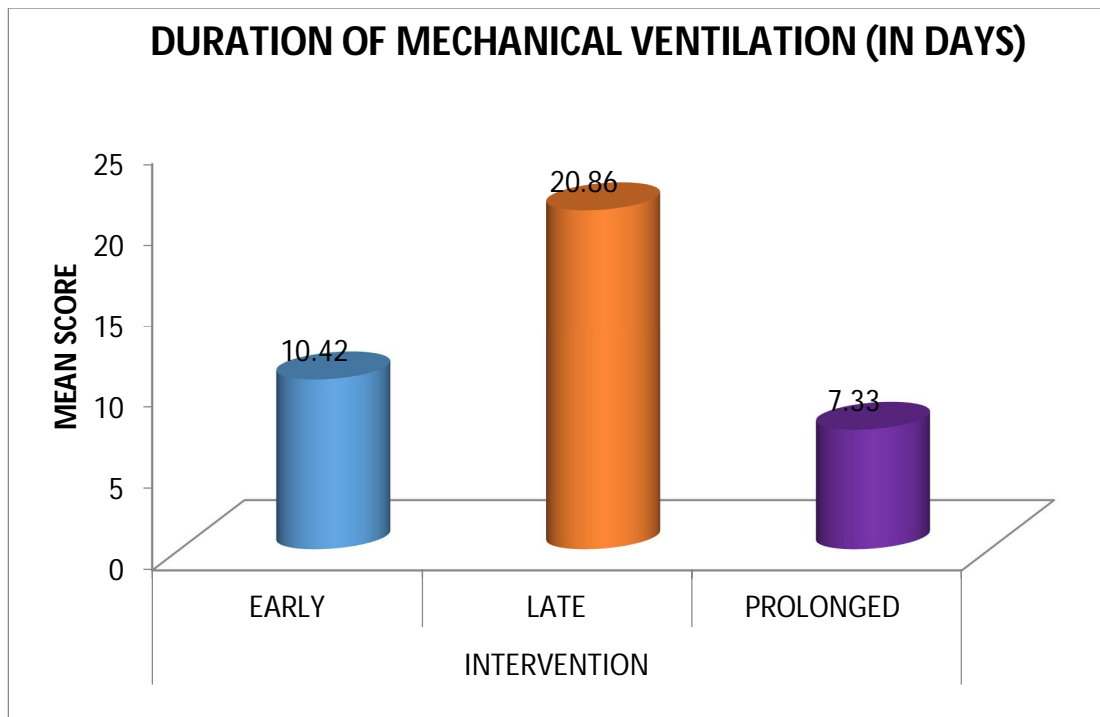


Fig 26 bar chart showing total duration of mechanical ventilation in days among all patients

Among the early tracheostomy group, mean duration of ventilation is 10 days when compared to 20 days of late tracheostomy group. p value is 0.001, which is statistically significant.

**TABLE-13 IMMEDIATE OUT COME(AT THE TIME OF DISCHARGE)
vs AGE DISTRIBUTION**

AGE GROUP	OUTCOME									
	Complication		Residual Paralysis		Improved		Expired		TOTAL	
	N	%	N	%	N	%	N	%	N	%
≤ 20	0	0	0	0	4	4.94	1	6.67	5	5.00
20 - 30	2	100	0	0	21	25.93	1	6.67	24	24.00
30 - 40	0	0	0	0	21	25.93	6	40.00	27	27.00
40 - 50	0	0	0	0	9	11.11	2	13.32	11	11.00
50 - 60	0	0	2	100	19	23.46	4	26.67	25	25.00
60 - 70	0	0	0	0	7	8.64	1	6.67	8	8.00
TOTAL	2	100	2	100	81	100	15	100	100	100
Chi square	15.64									
p-value	0.41									
Significant	Not Significant									

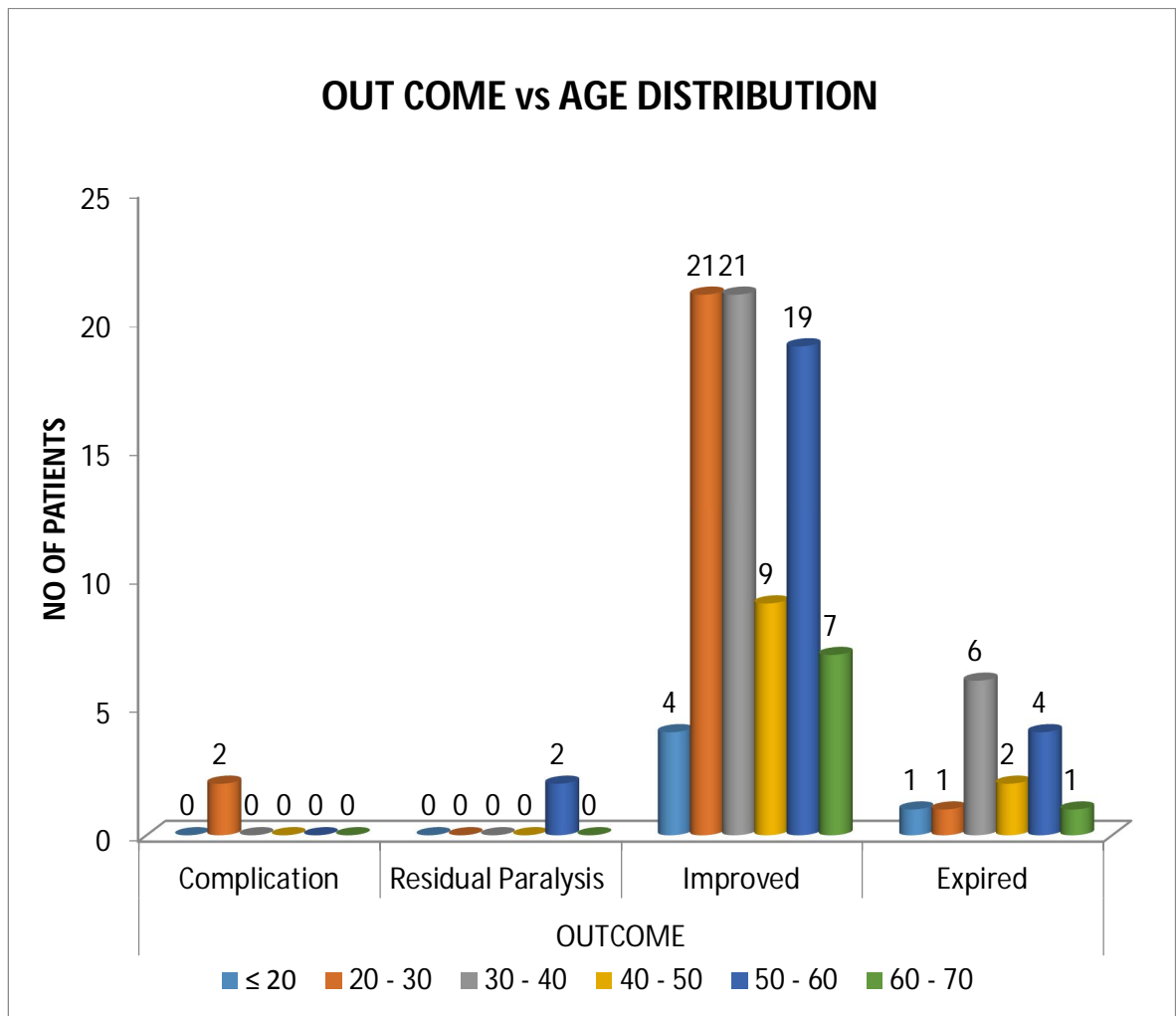


Fig 27 bar diagram depicting various outcomes against age distribution.

Among the total study group, two patients in the age group 20-30 yrs landed up in complications. 2 patients in age group 50-60 had residual paralysis. 6 patients in age group 30-40 yrs expired contributing to 40% followed by 4 patients in age group of 50-60 yrs contributing to 26.67%. On an average patients in the age group of 20-40 years improved well contributing to 51%. p-value is 0.41, statistically not significant.

**TABLE-14 : VDL1(WITHIN ONE MONTH AFTER DISCHARGE) vs AGE
DISTRIBUTION**

AGE GROUP	VDL1													
	Complication		Expired		Glottic Injury		Normal		Operation		Supra glottic Injury		TOTAL	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
≤ 20	1	12.50	1	5.88	1	12.50	2	3.33	0	0	0	0	5	5.00
20 - 30	5	62.50	1	5.88	2	25.00	13	21.67	0	0	3	60.00	24	24.00
30 - 40	1	12.50	6	35.29	1	12.50	16	26.67	1	50.00	2	40.00	27	27.00
40 - 50	0	0	2	11.76	1	12.50	8	13.33	0	0	0	0	11	11.00
50 - 60	1	12.50	6	35.29	3	37.50	14	23.33	1	50.00	0	0	25	25.00
60 - 70	0	0	1	5.88	0	0	7	11.67	0	0	0	0	8	8.00
TOTAL	8	100	17	100	8	100	60	100	2	100	5	100	100	100
Chi square		23.94												
p-value		0.52												
Significant		Not Significant												

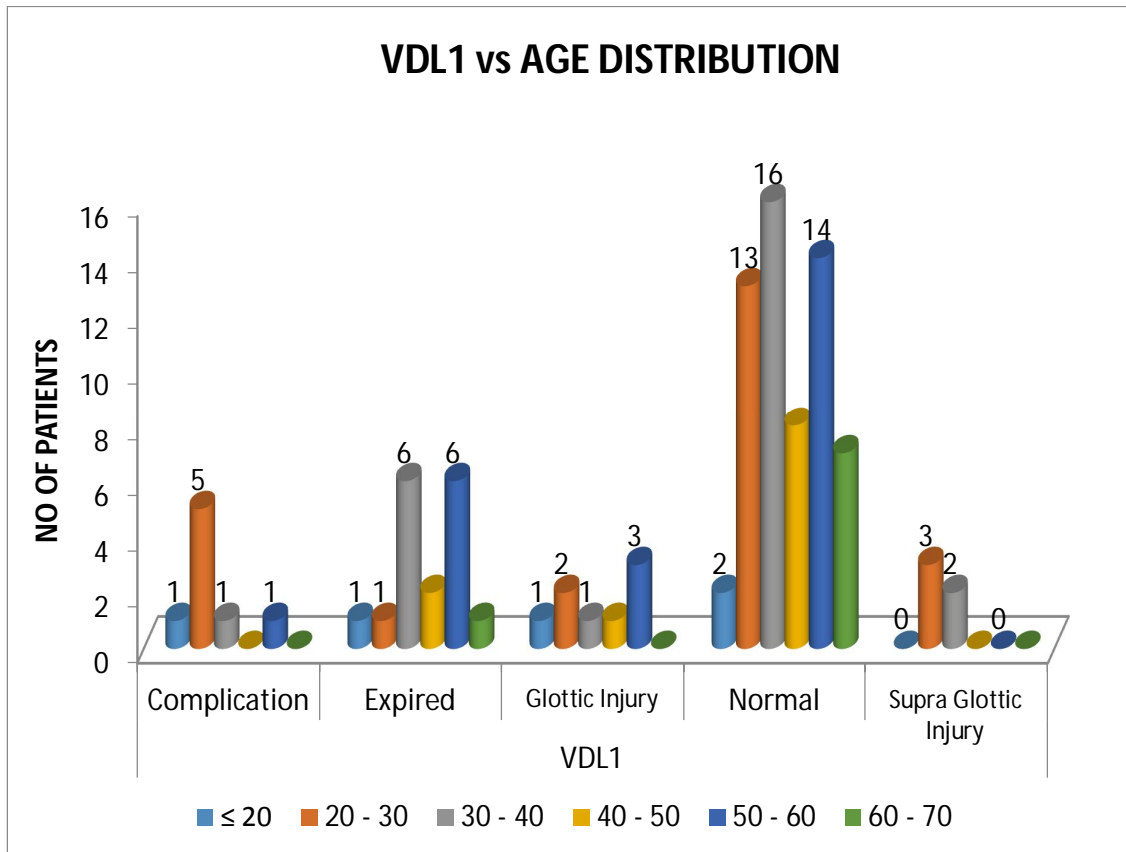


Fig 28 bar diagram showing findings during videolaryngoscopy done within one month of discharge among various age groups.

Of various injuries glottis injury is found to be common around 37.50% followed by supraglottic injury around 60%.glottic injury is common in 50-60 years compared to 20-30 years age group in which supraglottic injury is common. Of all the patients, 8 landed in complications ,developed subglottic and tracheal stenosis contributing to 8% and its more common contributing 62.50% in the age group of 20-30 years. Of those 8 patients 2 were operated.by around one month after discharge 17% were found to be expired .

TABLE-15 : IMMEDIATE OUT COME vs DIAGNOSIS

DIAGNOSIS	Complication		Residual Paralysis		Improved		Expired	
	N	%	N	%	N	%	N	%
Medical	0	0	0	0	15	18.52	2	13.33
Neurological	0	0	2	100	16	19.75	6	40.00
RTA	0	0	0	0	4	4.94	1	6.67
Toxicology	2	100	0	0	16	19.75	6	40.00
TOTAL	2	100	2	100	81	100	15	100
Chi square	11.22							
p-value	0.26							
Significant	Not Significant							

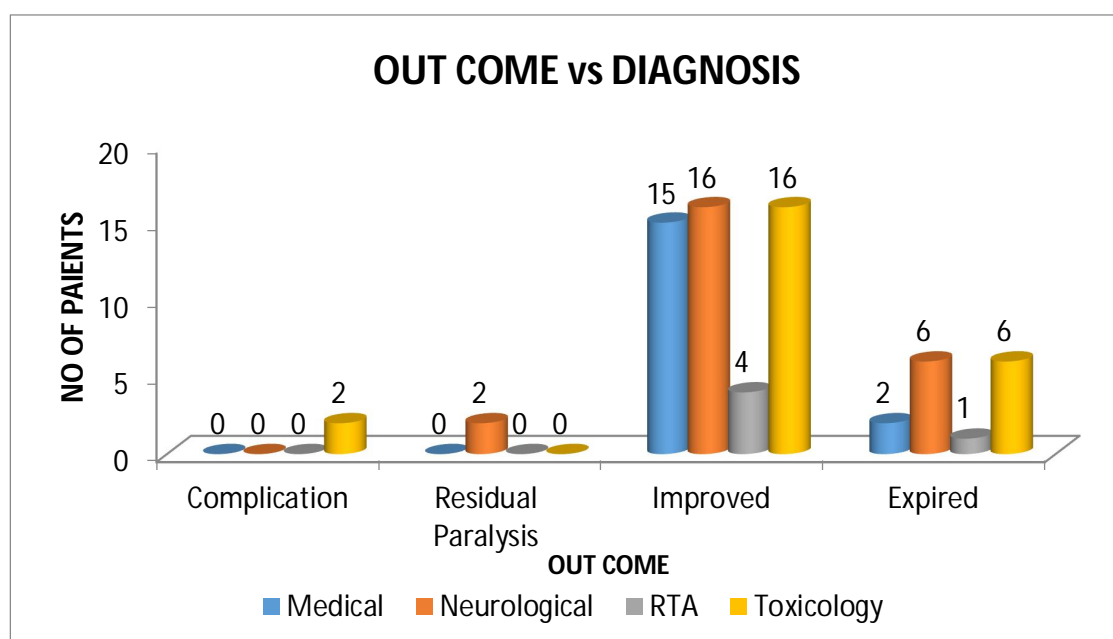


Fig 29 bar diagram depicting outcomes against various diagnosis of patients

Patients diagnosed to have neurological etiology and toxicology patients contributing to 40% each of respective study group are found to be expired when compared to patients with other diagnosis. 2% of toxicology patients have developed complications at the time of discharge itself

TABLE-16 : VDL1 vs DIAGNOSIS

AGE GROUP	VDL1													
	Complication		Expired		Glottic Injury		Normal		Operation		Supra glottic injury		TOTAL	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Medical	0	0	2	11.76	0	0	15	25.00	0	0	0	0	17	17.00
Neurological	1	12.50	7	41.18	2	25.00	14	41.73	0	0	0	0	24	24.00
RTA	0	0	1	5.88	0	0	4	6.67	0	0	0	0	5	5.00
Toxicology	7	87.50	7	41.18	6	75.00	27	45.00	2	100	5	100	54	54.00
TOTAL	8	100	17	100	8	100	60	100	2	100	5	100	100	100
Chi square		18.65												
p-value		0.23												
Significant		Not Significant												

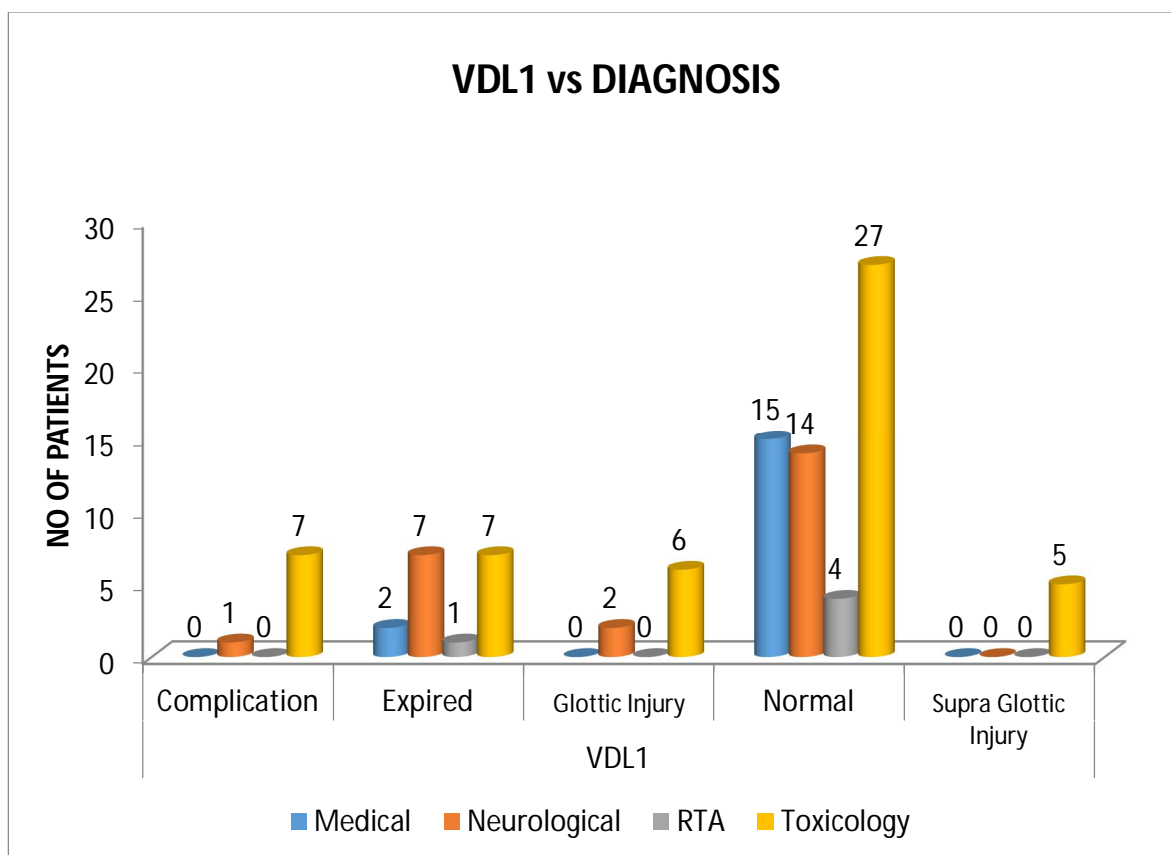


Fig 30 bar diagram showing videolaryngoscopy findings within one month after discharge against various diagnosis.

Of all patients developing complications ,in toxicology 7 patients out of 8 were the most common to land up in complications namely subglottic and tracheal stenosis ,of which two were operated. Thus toxicology patients contribute to 87.50% of total study group to develop complications of 28 patients of toxicology group , 6 patients developed glottic injury while in the same group supraglottic injury is also commonly seen in 5 patients.

TABLE-17 : VDL1 vs INTERVENTION

VDL1	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Complication	0	0	3	12.00	5	17.86
Expired	6	12.77	5	20.00	6	21.43
Glottic Injury	0	0	2	8.00	6	21.43
Normal	40	85.10	14	56.00	6	21.43
Operation	0	0	1	4.00	1	3.57
Supraglottic Injury	1	2.13	0	0	4	14.29
TOTAL	47	100	25	100	28	100
Chi square	39.27					
p-value	0.001					
Significant	Significant					

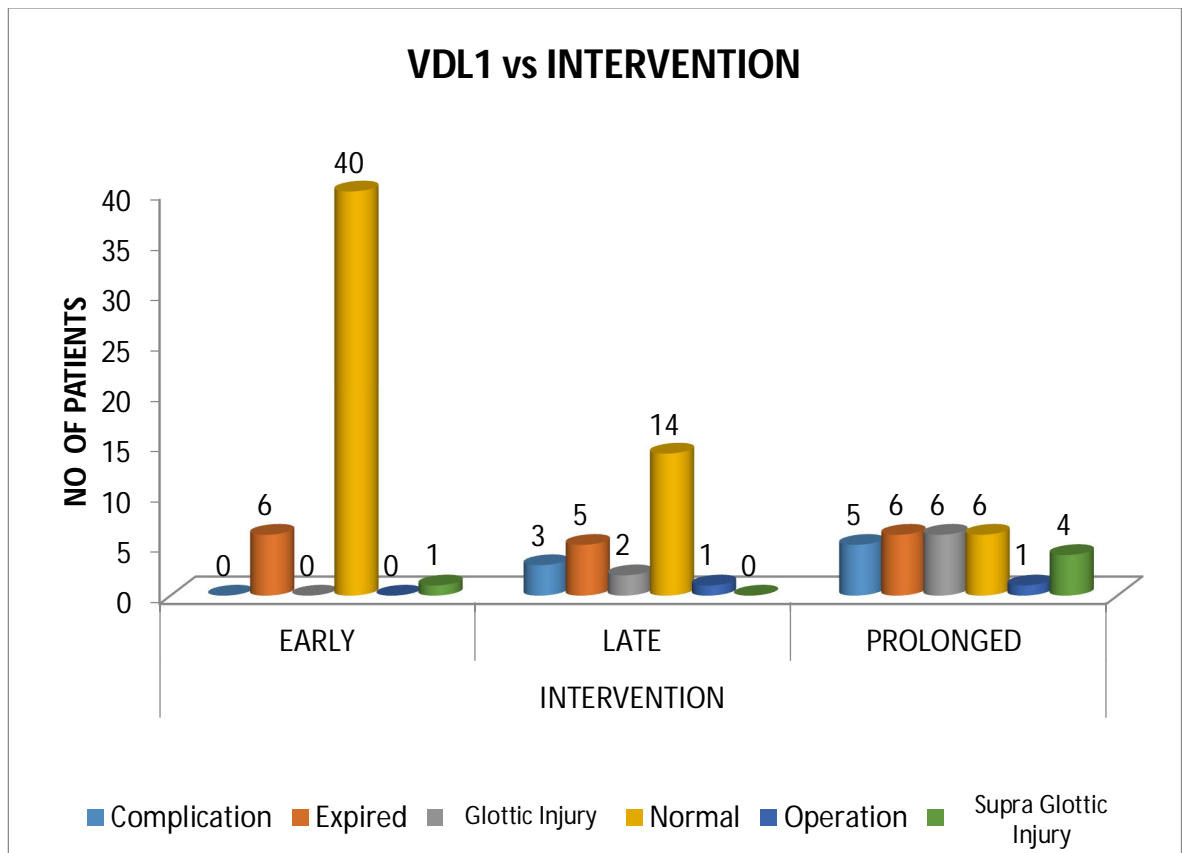


Fig 31 bar diagram showing videolaryngoscopy findings within one month after discharge among the three study groups.

5 patients of Prolonged intubation contributing to 17.86% and 3 patients of LT group around 12% developed complications when ET group had no complications. Glottic injury contributing to 21.43% and supraglottic injury around 14.29% developed during intubation is common among PROL.INT group followed by LT group. p value is 0.001, which is statistically significant.

TABLE-18 :
VDL2 (6 MONTHS AFTER DISCHARGE) vs INTERVENTION

VDL2	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Complication	1	2.13	5	20.00	3	10.71
Expired	6	12.77	6	24.00	6	21.43
Normal	39	82.97	13	52.00	17	60.71
Operation	1	2.13	1	4.00	2	7.14
TOTAL	47	100	25	100	28	100
Chi square	11.08					
p-value	0.09					
Significant	Not Significant					

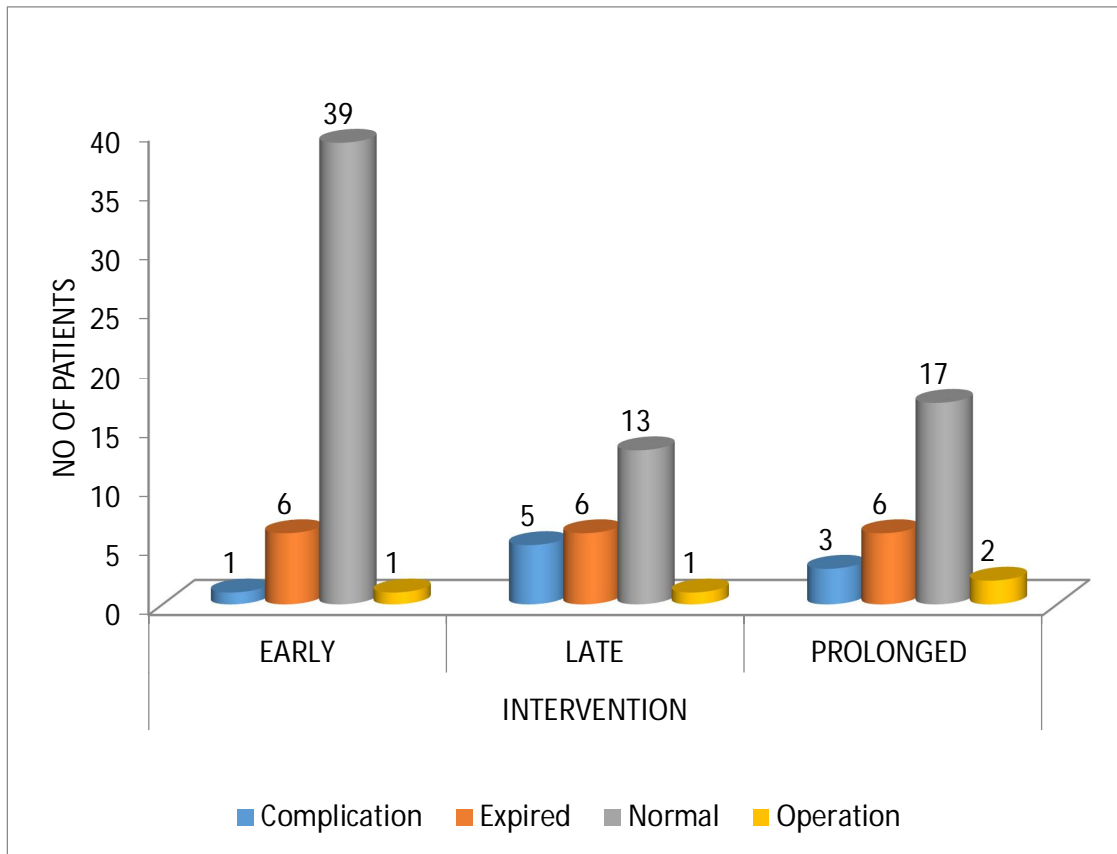


Fig 32 bar diagram showing videolaryngoscopy findings done by 6 months after discharge among all the groups.

All the mucosal injuries during intubation are found to be resolved among the prolonged intubation group. five patients in late tracheostomy group developed complications like failed decannulation and tracheostoma ulceration. 82.97% of ET group were normal when compared to 52% of LT group. Out of prolonged intubation group developing complications, 7.14% were operated while 10.71% remained to have stenosis without any intervention.

TABLE-19 : VDL1 vs VDL2

VDL1	VDL2				
	Complication	Expired	Normal	Operation	TOTAL
Complication	4	0	2	2	8
Expired	0	17	0	0	17
Glottic Injury	1	0	7	0	8
Normal	4	1	54	1	60
Operation	0	0	1	1	2
Supraglottic Injury	0	0	5	0	5
TOTAL	9	18	69	4	100

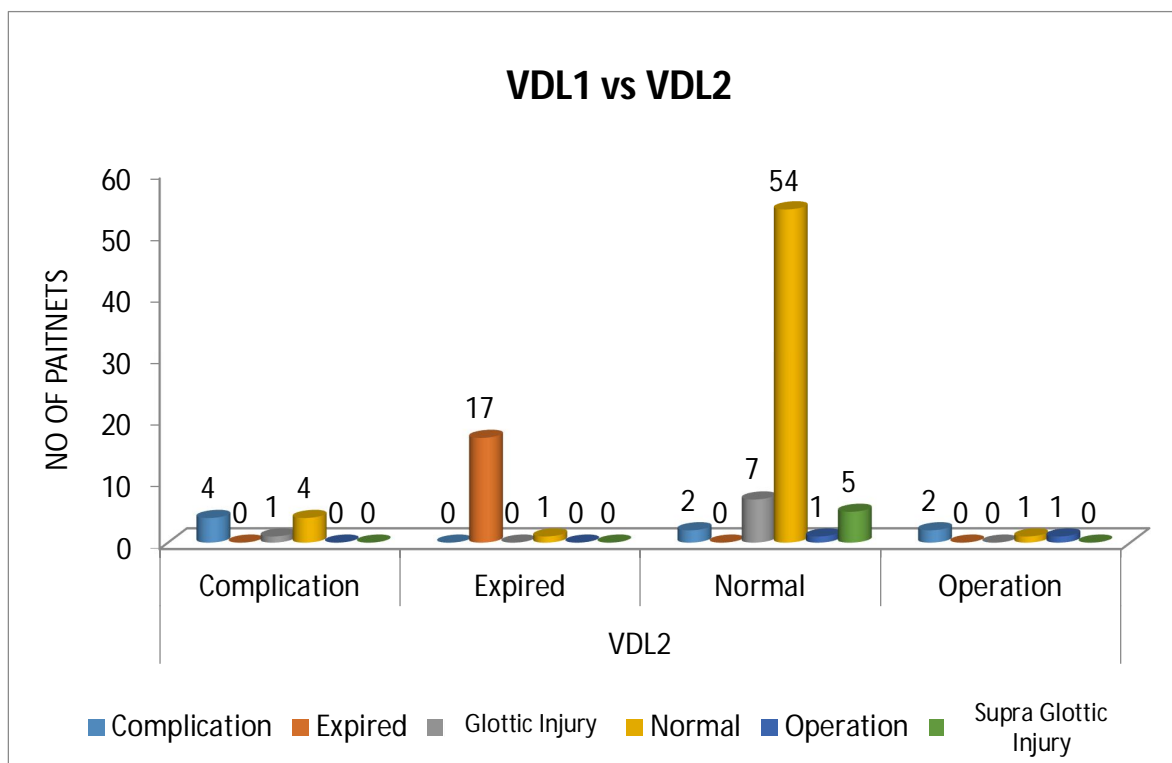


Fig 33 bar diagram showing difference between videolaryngoscopy findings by one month and six months after discharge.

Complication rate have increased from 8 patients to 9 by six months after discharge. Videolaryngoscopy findings became normal for additional nine patients in addition to 60 patients who had normal VLS findings during first time. Two patients had secondary suturing for failed decannulation. In addition two patients had tracheal resection and anastomosis

TABLE-20 : TUBE CHANGE

	EARLY	LATE
N	41	20
Median	3.00	4.00
Mode	2.00	4.00
Min	1	2
Max	7	9

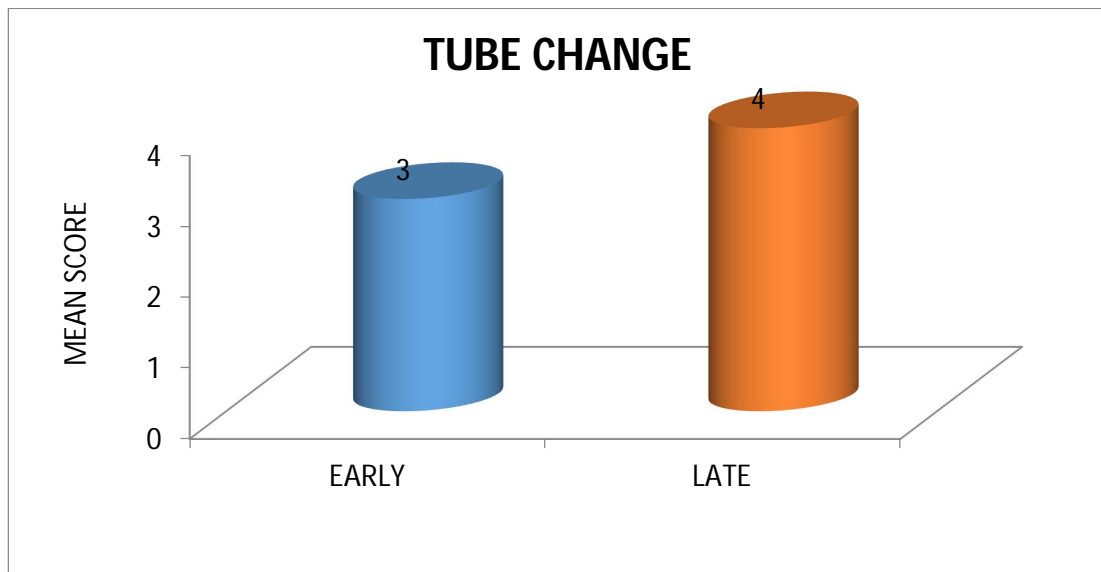


Fig 34 bar diagram showing average no of days taken for metallic tube change.

ET group had tube change on an average 3rd day while LT group had it on 4th day.

TABLE-21 : DAYS STAY IN ICU

	INTERVENTION		
	EARLY	LATE	PROLONGED
N	42	21	15
MEAN	13.07	27.00	8.80
SD	7.07	10.62	4.02
f-Value	30.43		
p-Value	0.000		
Significant	Significant		

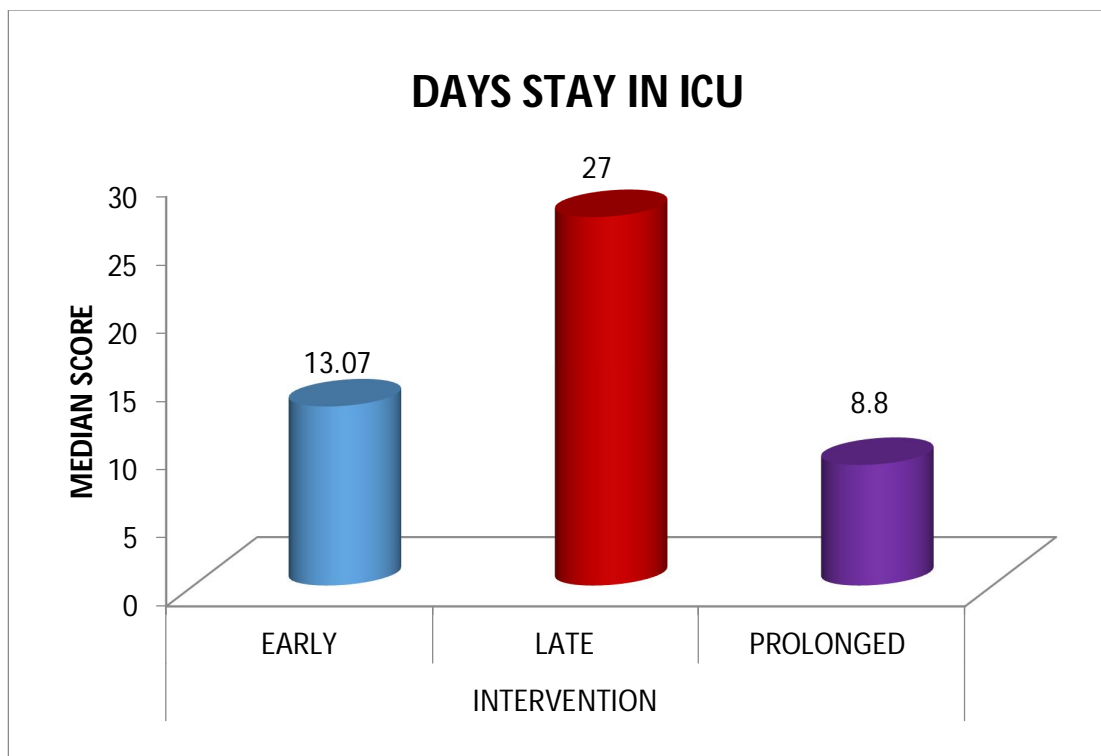


Fig 35 bar diagram depicting average number of days of ICU stay among all the groups.

ET group had to stay 13 mean days when compared to 27 mean days of LT group. p value is 0.000, which is statistically significant.

TABLE-22 : DAYS STAY IN HOSPITAL

	INTERVENTION		
	EARLY	LATE	PROLONGED
N	41	20	21
Mean	19.29	32.60	13.95
sd	8.76	10.59	9.53
f-Value	21.69		
p-Value	0.000		
Significant	Significant		

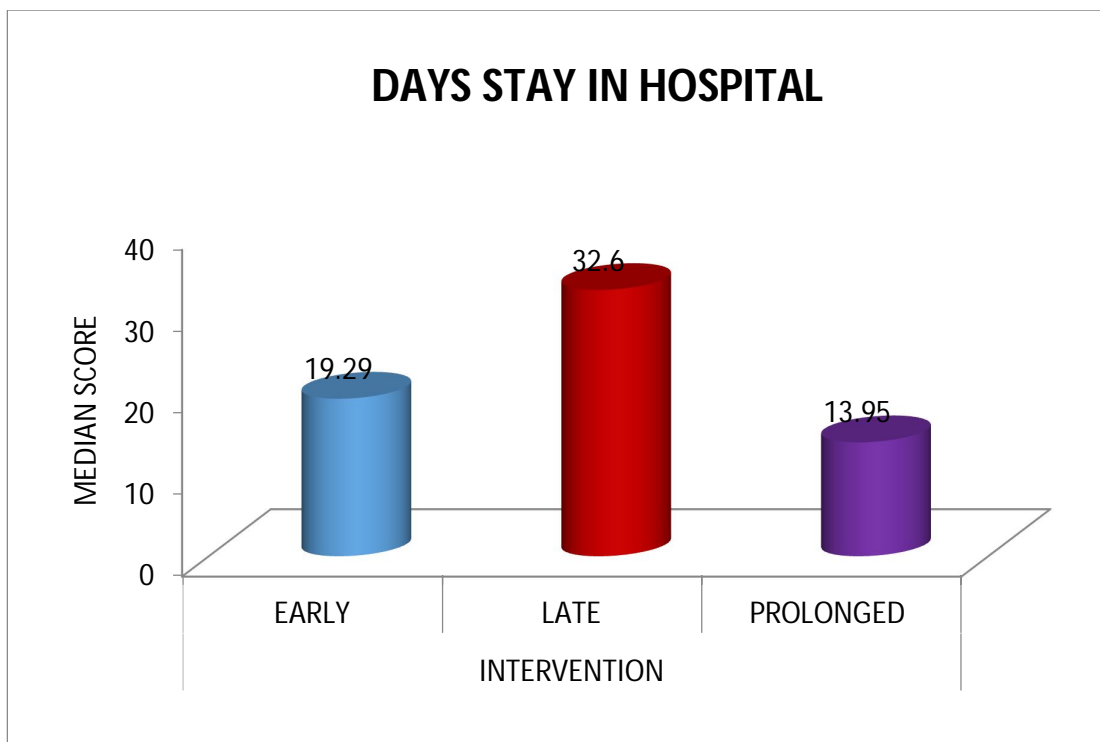


Fig 36 bar diagram showing total number of days in hospital among all the groups.

ET group patients had to stay on an average 19 days when compared to 32 mean days for LT group. p value is 0.000, which is statistically significant.

TABLE-23 : INTERVENTION vs DIAGNOSIS

DIAGNOSIS	INTERVENTION					
	EARLY		LATE		PROLONGED	
	N	%	N	%	N	%
Medical	9	19.15	5	20.00	3	10.71
Neurological	10	21.28	10	40.00	4	14.29
RTA	3	6.38	1	4.00	1	3.57
Toxicology	25	53.19	9	36.00	20	71.43
TOTAL	47	100	25	100	28	100
Chi square	8.25					
p-value	0.22					
Significant	Not Significant					

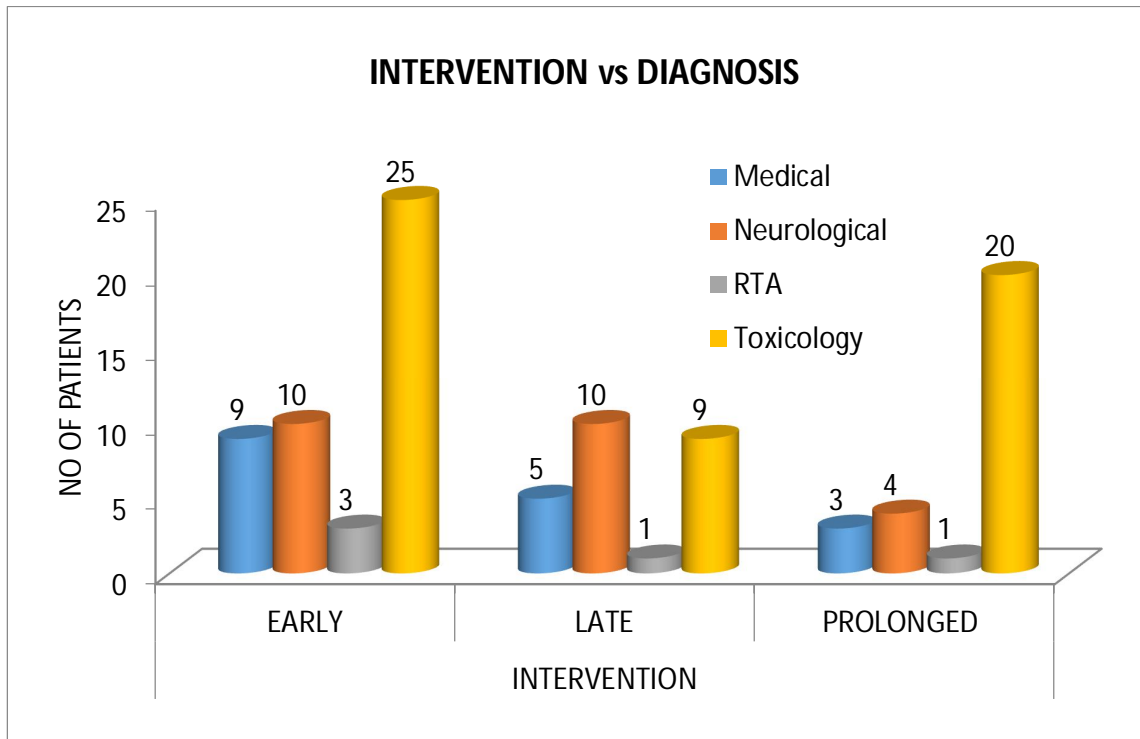


Fig 37 bar diagram showing intervention among various groups with different diagnosis.

53.19% of toxicology patients have underwent early tracheostomy whereas 71.43% have remained intubated. 40% of neurological patients had late tracheostomy

Discussion

DISCUSSION

The present study was conducted from May 2016 to Oct 2017. 100 patients of both sexes were included in the study. Males are more common contributing 70% to the total study group. Age group ranged from 20-70 years with mean age 40±10 years. Similar results were given by Sanabria A et al. In her cohort study, 163 (62%) were male, and the median age was 59±17 years. Almost one-third (36%) of patients needed mechanical ventilation longer than 7 days. . In a study conducted by Tareq Mahafza et al, Out of 106 cases, there were 74 (70%) males and 32 (30%) females, and their age ranged from 2 months to 90 yr with a mean age of 46.5 yr. Boubaker Charra et al in his study of Tracheostomy vs prolonged ET in ICU patients found the mean age was 41 ± 11 years. In a retrospective study by Chia-Lin Hsu et al 163 patients were included out of which 93 male and 70 female

Of the total study group majority of patients around 26% lie in the age group of 30-40 years followed by 50-60yrs age group. In prolonged intubation group much of the patients around 35% were in age group between 20-30 yrs. in early tracheostomy group not much of the difference between age groups noted whereas in LT group 32% of patients lie in the age group of 50-60 years. A different observation is made in a retrospective study by HSU et al showing mean age 70 years, range 19–104 years.

The mean GCS score at the time of intubation of ET group is 7 when compared to 6 of LT group and 6 of prolonged intubation group. p value is 0.61, not significant. Lanza et al. retrospectively studied 47 head injury patients to examine the predictive value of the GCS for tracheostomy. They were categorised according to their GCS rating, 34 had a $GCS \leq 7$ and 13 patients had $GCS > 7$. They found that in patients with $GCS \leq 7$, the likelihood of tracheostomy is significantly greater. Ross and colleagues found age > 40 years, $GCS \leq 7$ and alveolar-arterial oxygen gradient ($A-a O_2$) ≥ 100 to 150 were good predictors of prolonged mechanical ventilatory support. Gurkin et al found $GCS \leq 8$ on presentation and Injury Severity Score ≥ 25 are highly predictive of tracheostomy similar to our study.

The mean GCS score at third day of intubation of all patients were 6, p value is 0.44, found insignificant.

Of the total 47 patients of ET group 8 were reintubated which contributes 17%. Among the LT group patients 12 reintubated out of 13 patients contributing around 48%, whereas in prolonged intubation group 14 reintubated out of 28 which contributes to maximum around 50%. p value is 0.003, which is statistically significant. Thus reintubation attempts are more common in prolonged intubation group, followed by LT group, while least common in early tracheostomy. This is similar to a retrospective study conducted by Koh et al. He included 49 patients, 20 of which were victims of trauma, who required admission to the neurosurgical ICU.

In this study, the reintubation rate was 22% despite meeting weaning criteria. Among the predictors of failed extubation were low Glasgow Coma Scale (GCS) and excessive airway secretions

Of the total 100 patients, tracheostomy was done in 72 patients of which, early tracheostomy(within one week of intubation) was done in 47 patients and late tracheostomy (done anytime after one week) was done in 25 patients. Remaining 28 patients continued to be intubated. p value is 0.17, not significant.so once patient is anticipated of prolonged ventilation ,immediate tracheostomy should be done as we know that tracheostomy has the advantages of reducing dead space ventilation, reducing airway resistance, decreasing the work of breathing thereby it promotes weaning of mechanical ventilation at the earliest allows patient to talk ,swallow and reduces the risk of aspiration promoting easy withdrawal from ventilator.

One patient of LT group denied tracheostomy.one among ET group contributing to 2% and 5 out of prolonged intubation group contributing to 17.86% expired. One patient of late tracheostomy group contributing to 4% developed ventilator associated pneumonia.17 out of 28 patients of PROL.INT group got improved contributing to 60.71% whereas remaining study patients i.e., 95.74% of ET group and 88% of LT group had to undergo tracheostomy as their general condition remained the same or got worsened. p value is 0.001,statistically significant. However there is no appreciable difference in the incidence of

pneumonia between study groups. This outcome is similar to Sugerman et al study who also did not find appreciable difference in incidence of pneumonia in ET versus LT. However Rumbak et al established remarkable 80% fewer pneumonias in ET group in his study. Moller et al found decrease in VAP after ET (27 vs 72%) in contrast to our study. Hsu et al was not able to demonstrate decrease in pneumonia in ET similar to our study. Yet another study which gave similar results are done by Boudika et al. They studied no difference in pneumonia between ET and continued intubation (58 vs 61%), delay in VAP occurrence (6.7 ± 1.8 vs 9.2 ± 2.3) and speedier recovery from ventilator dependence (6 ± 4.7 vs 11.7 ± 6.7)

Among total 72 patients who underwent tracheostomy, prolonged ventilation remains to be more common cause contributing to 41.6%, followed by respiratory insufficiency contributing to 30.5%. p value is 0.002, significant.

Of the ET group 4 patients had tube block contributing to 8.51% out of 47 patients. 2 out of 25 LT group patients had tube displacement contributing to 8%. 87.23% of ET group and 84% of LT group had no complications intra operatively. Thus p value is 0.37, which is statistically not significant. In a retrospective study by HSU et al the most common immediate complication of tracheostomy was bleeding (moderate bleeding in 11 [6.7%] and minor bleeding in 46 [28.2%]), followed by subcutaneous emphysema (3 [1.8%]; in two patients this occurred together with bleeding and in one patient it occurred together with air leakage) and tube obstruction in 3 patients [1.8%])

Of the 100 patients ,47 had early tracheostomy contributing to 65.28% while 25 patients had late tracheostomy contributing to 34.72%. similar study is conducted by Koji Hosokawa et al .they studied timing of tracheotomy in ICU patients: It was a systematic review of randomized controlled trials. Of the 142 studies identified in the search, including a total of 2,689 patients, The tracheotomy rate was significantly greater with early than with late tracheotomy 87 % versus 53 %.,. In a study conducted by Tareq Mahafza et al, Early tracheostomy (within 3 weeks of an ICU admission) was done in 70 (66%) patients while 26 (24.5%) patients had the tracheostomy done in the 4th week, in the 5th week tracheostomy done in 6 (5.7%) done, 3 (2.8%) cases done in the 6th week, and only 1 (.9%) case had tracheostomy in the 7th week of tracheal intubation. .

Based on the diagnosis for intubation, 53.19% of toxicology patients have underwent early tracheostomy to the maximum whereas 71.43% have remained intubated to the greatest among all the patients .40% of neurological patients had late tracheostomy to the maximum. Hsu et al found in his study that the indications for intubation can be categorised into pulmonary (n = 107), infectious (n = 18), neurological (n = 28) and circulatory (n = 10) disease.

Immediate outcome at the time of discharge -Among ET group 42 patients improved contributing to 89.36% compared to 72% of LT group .4 among ET and 5 among LT group expired, whereas 6 out of 28 patients of prolonged intubation group contributing to 21.43% died ,one each of ET and LT group had residual

paralysis. p value is 0.41, statistically not significant. Thus there is no difference in mortality rate between two study groups. Similar results are given by Arabi et al. He studied no difference in overall hospital mortality (17 vs 14%) between two groups of ET and LT. In contrast to Rumbak et al study. He studied 50% reduction in mortality rate after ET (19 vs 37%) and also concluded more patients died of ventilator associated pneumonia in LT more than ET (9 vs 2). Kollef et al found similar difference (13.7 vs 26.4). Hsu et al also studied mortality rate among ET and LT patients, found rate to be reduced in ET patients (14.5 vs 28.3).

Moreover he did not find any difference in hospital mortality rate (44.5 vs 54.7%). Tareq Mahafza et al also found out that The rate of ventilator-associated pneumonia among patients was 33, more common with patients who had late tracheostomy (41.7%) than with early tracheostomy patients (28.6%). Different observation was made by Stauffer in his study. He did a prospective survey including 150 patients showed that prolonged intubation provokes less tracheal complications than tracheotomy (62% versus 66%), especially tracheal stenosis (19% versus 65%). Tracheomalacia as well as esophageal fistulas are more common with tracheotomy than with intubation. In a retrospective study by Hsu et al The incidence of complications did not differ significantly between the successful weaning and failure-to-wean groups (early complications: 38.5% versus 37.6%, $P = 1.0$; late complications: 6.4% versus 9.4%, $P = 0.6$) which is similar to our study.

Among the early tracheostomy group, mean duration of ventilation is 10 days when compared to 20 days of late tracheostomy group. p value is 0.001, which is statistically significant. This outcome is similar to Rumbak et al study. Rumbak et al did a prospective study in 120 patients comparing early versus late tracheostomy. He found reduced time of mechanical ventilation in early tracheostomy group (<48 hrs) 7.6 ± 4.0 vs 17.4 ± 5.3 days (late tracheostomy group >48 hours). Flatten et al did a study on 461 patients retrospectively and found reduced median number of days on ventilator after ET (4.7 vs 14.7 days) which is similar to our study. Hsu et al included 163 medical ICU patients in his study, divided them into successful and failed weaning. Patients on intubation for >21 days had decreased rate of successful weaning (31.5 vs 56%). Moreover patients who had early tracheostomy had shorter weaning periods (19 vs 44.3 days). So they had to continue on ventilator for a longer time than early tracheostomy patients producing similar outcome like our study. Lesnik and coworkers retrospectively studied 101 patients with blunt multiple trauma. 32 patients were tracheostomized within 4 days of intubation. They found reduced duration of mechanical ventilation and reduced incidence of nosocomial pneumonia in ET group.

Immediate outcome versus age -Among the total study group, two patients in the age group 20-30 yrs landed up in complications. 2 patients in age group 50-60 had residual paralysis. 6 patients in age group 30-40 yrs expired contributing to 40% followed by 4 patients in age group of 50-60 yrs contributing to 26.67%. on an

average patients in the age group of 20-40 years improved well contributing to 51%. pvalue is 0.41, statistically not significant.

VLS within one month after discharge -Of various injuries glottic injury is found to be common around 37.50% followed by supraglottic injury around 60%. glottic injury is common in 50-60 years compared to 20-30 years age group in which supraglottic injury is common. Of all the patients, 8 landed in complications, developed subglottic and tracheal stenosis contributing to 8% and its more common contributing 62.50% in the age group of 20-30 years. Of those 8 patients 2 were operated. by around one month after discharge 17% were found to be expired .

Immediate outcome versus diagnosis -Patients diagnosed to have neurological etiology and toxicology patients contributing to 40% each of respective study group are found to be expired when compared to patients with other diagnosis. 2% of toxicology patients have developed complications at the time of discharge itself

VLS at the time of discharge versus diagnosis -Of all patients developing complications, in toxicology 7 patients out of 8 were the most common to land up in complications namely subglottic and tracheal stenosis ,of which two were operated. Thus toxicology patients contribute to 87.50% of total study group to develop complications. Of 28 patients of toxicology group , 6 patients developed glottic injury while in the same group supraglottic injury is also commonly seen in 5 patients.

VLS findings at the time of discharge among various groups -5patients of Prolonged intubation contributing to 17.86% and 3 patients of LT group around 12% developed complications when ET group had no complications. Glottic injury contributing to 21.43% and supraglottic injury around 14.29% developed during intubation is common among PROL.INT group followed by LT group. p value is 0.001, which is statistically significant. Another study conducted by Tareq Mahafza et al have found that 12 (33.3%) of patients who had late tracheostomy did land up in airway injuries while 16 (22.9%) of patients with early tracheostomy had airway injuries. This differs from our study as the LT or ET group had invariably less or no airway injuries than PROL.INT group. In a retrospective study by Hsu et al the most common complication was bleeding (4 [2.5%]), followed by air leakage (3 [1.8%]) and tracheal stenosis (2 [1.2%]).

VLS findings by six months after discharge among study groups- All the mucosal injuries during intubation are found to be resolved among the prolonged intubation group. Five patients in late tracheostomy group developed complications like failed decannulation and tracheostoma ulceration .82.97% of ET group were normal when compared to 52% of LT group. Out of prolonged intubation group developing complications, 7.14% were operated while 10.71% remained to have stenosis without any intervention. Total 18 patients out of 100 have expired by the end of six months. Of which 12.77% of ET group, 24% of LT group and 21.43% of prolonged intubation group have expired. Thus mortality rate is higher among PROL.INT group and LT group. Similar observation is made

by Tareq Mahafza et al. the overall mortality rate was 26 (24.5%), notably higher death rate 13 (36.1%) among late tracheostomy than early tracheostomy which is 17.1%. Similarly Rodriguez reported 0%, and Berlaak 3%. Mortality rate is minimal after tracheostomy. Similar to our study Koji Hosokawa conducted a systematic review of randomized controlled trials regarding Timing of tracheotomy in ICU patients. He found out reduced long term mortality rate in early tracheostomy patients. Andriola et al found out that early tracheostomy had reduced risk of mortality as compared with patients subjected to a late tracheostomy. These patients were followed at the longest follow-up time available in seven studies that measured mortality (ranging from 28 days to two years of follow -up).

VLS 1 vs VLS 2-Complication rate have increased from 8 patients to 9 by six months after discharge. Videolaryngoscopy findings became normal for additional nine patients in addition to 60 patients who had normal VLS findings during first time. Two patients had secondary suturing for failed tracheostoma closure. In addition two patients had tracheal resection and anastomosis

ET group had tube change on an average 3rd day while LT group had it on 4th day.

ET group had to stay 13 mean days in ICU when compared to 27 mean days of LT group. p value is 0.000, which is statistically significant. This is similar to Rumbak et al study where they found reduced length of stay in intensive care patients after early tracheostomy (4.8 ± 1.4 versus 16.2 ± 3.8 days). Similarly Flatten et al also studied decreased length of stay in ICU patients after early tracheostomy

(<7 days) compared with LT (6.8 vs 12.7 days). Moller et al also compared ICU patients before and after tracheostomy. He found reduced ICU length of stay (16.7 ± 1.0 vs 26 ± 1.3 days) as well as shortened hospital stay (22.8 ± 1.2 vs 33.4 ± 1.7 days) in patients whom had early tracheostomy. HSU et al also concluded in his study that early tracheostomy is better than late tracheostomy is minimizing length of stay (10.8 vs 14.2 days). Arabi et al also confirmed ET better than LT with respect to length of stay (10.9 ± 1.2 vs 21.0 ± 1.3 days) and also found no difference in overall hospital length of stay. Suzuki et al and Kusunoki et al studied 100 patients and found ET better than LT. Tareq Mahafza et al also found out that Early tracheotomy was associated with early weaning from ventilator, a shorter ICU stay and a shorter duration of sedation ($p < 0.05$). The length of stay in the ICU for these patients was 41 days, ranging from 3 to 28 weeks (26:47 days early to late tracheostomy ratio) which is similar to our study. Same observation was noted in a retrospective analysis by Bickenbach et al, early tracheostomy was found to reduce the duration of artificial ventilation as well as ICU length of stay. Rodriquez et al found similar observation of reduced time of mechanical ventilation, shorter ICU stay and shorter hospital stay among early tracheostomy group. Meng L and colleagues found that ET might be able to reduce the duration of sedation but did not significantly alter the mortality, incidence of VAP, duration of MV and length of ICU stay in contrast our study.

ET group patients had to stay in hospital on an average 19 days when compared to 32 mean days for LT group. p value is 0.000, which is statistically significant. This is in contrast to Arabi et al study which says no difference in

overall length of hospital stay between ET and LT group. Moller et al compared ICU patients before and after tracheostomy and found shortened hospital stay(22.8 ± 1.2 vs 33.4 ± 1.7 days) in patients whom had early tracheostomy similar to our study. Armstrong and colleagues also found early tracheostomy was associated with less ICU stay and reduced hospital stay in a retrospective study of blunt trauma patients.

Summary & Conclusions

SUMMARY & CONCLUSION

A comparative study on endotracheal intubation versus tracheostomy in patients requiring prolonged ventilation was taken up. Study population was split into prolonged intubation ,early tracheostomy and late tracheostomy groups. Tracheostomy is one of the most common surgical procedure done in intensive care units. From our study we conclude that

1. GCS less than 7 appears to be a predictable indicator for patients requiring prolonged mechanical ventilation
2. Reintubation attempts are studied to be common in prolonged intubation group , followed by late tracheostomy and least in early tracheostomy group. Sudden desaturation, tube block and excessive tracheal secretions are found to be common causes for repeated intubation. this in turn provokes airway injury like supraglottic laryngeal injury, supraglottic stenosis, mucosal ulceration and oedema of epiglottis, vocal cord paralysis, glottic injury and ulceration, subglottic stenosis, tracheal stenosis and ventilator associated pneumonia. Thus reason for reintubation should be individualized and staff nurses should be educated about frequent suctioning and tube care.
3. In hospital mortality rate is high among prolonged intubation group than other groups, however long term mortality rate remains the same between the study groups.

4. Incidence of ventilator associated pneumonia was very minimal, so association of VAP with study groups could not be analysed in our present study.
5. Regarding intra operative complications, bleeding has been the single most common complication in tracheostomized patients. Tracheostomy tube block has been noted in the immediate post operative period. This could be avoided by adequate knowledge about suctioning.
6. Patients on prolonged intubation for more than 7-10 days are more prone for airway injuries such as supraglottic and glottic injuries and end up in long term complications like tracheal stenosis. Cuffed tubes should be of appropriate size and the cuff pressure to be maintained within 20mmHg. there are cuff pressure monitors available, which should be routinely used to avoid above complications.
7. From our study it is analysed that tracheostomy performed within 7 days after intubation was associated with shortened duration of mechanical ventilation and length of ICU and hospital stay than late tracheostomy group.
8. Thus tracheostomy might have resulted in earlier withdrawal of MV, a finding suggested by more number of ventilator-free days. We believe that the possibility of earlier withdrawal of MV, thereby decreasing the exposure of patients to its risks, is the prime factor responsible for the longer survival among the patients undergoing early tracheostomy

9. Tracheostomy should be carried out as soon as the need for prolonged airway support is expected. Limitations are lack of prospective, randomized controlled trials, physician bias and patients's pre-existing morbidities, which further confound the decisions regarding the exact timing of tracheostomy.
10. Thus by 7-10 days if patient could not be extubated, surgical tracheostomy should be planned.

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Annexures

MASTER CHART (1)

SL NO	NAME	AGE	SEX	NEW Diaganosis	DOA	GCS 1	DOI	GCS 3	Intubation Continued / Weaned	DOW	Re Intubation	DOD	INTN_TRACH	DOE	OUTCOME
1	Issac	45	MALE	Medical	23-03-17	8	23-03-17	7	continued	-	-	-	tracheostomy on 28-3-17	-	-
2	Vijaya	63	FEMALE	Medical	08-09-16	6	08-09-16	5	continued	-	-	-	Tracheostomy	-	-
3	Divya	26	FEMALE	Medical	28-06-16	7	28-06-16	7	continued	-	Yes	-	Trachestomy done	-	-
4	Narayanasamy	64	MALE	Medical	25-02-17	8	25-02-17	7	continued	-	-	-	Trachestomy done on 03-03-2017	-	-
5	Santhrika	35	FEMALE	Toxicology	04-06-16	5	04-06-16		continued	-	-	-	Trachestomy done on 10-06-2016	-	-
6	Murugan	40	MALE	Medical	09-02-17	8	09-02-17	7	continued	-	-	-	Trachestomy done on 14-02-2017	-	-
7	Shanmugavelu	59	MALE	Medical	01-03-17	8	01-03-17	7	continued	-	-	-	Trachestomy done on 4-03-17	-	-
8	Narayanasamy	66	MALE	Medical	03-03-17	8	03-03-17	7	continued	-	-	-	Trachestomy done on 7-3-17	-	-
9	Sakunthala	50	FEMALE	Medical	01-03-17	7	01-03-17	7	continued	-	-	-	Trachestomy done on 7-3-17	-	-
10	Sivakumar	37	MALE	Toxicology	03-07-16	8	03-07-16	7	continued	-	-	-	Trachestomy done on 06-07-2016	-	-
11	Vinoth	54	MALE	Toxicology	12-03-17	5	12-03-17	5	continued	-	-	-	Trachestomy on 18-3-17	-	-
12	Alamelu	33	FEMALE	Neurological	28-03-17	8	28-03-17	7	continued	-	-	-	Trachestomy done on 02-04-2017	-	-
13	Annadurai	60	MALE	Toxicology	03-01-17	9	03-01-17	8	continued	-	-	-	Tracheostomy	-	-
14	Suryakala	49	FEMALE	Neurological	05-08-16	8	05-08-16	7	continued	-	-	-	Trachestomy on 10-08-2016	-	-
15	Jeyakumar	45	MALE	Toxicology	21-10-16	8	21-10-16	7	continued	-	Yes	-	Trachestomy on 24-10-2016	-	-
16	Madanraj	30	MALE	Neurological	04-05-16	8	04-05-16	8	continued	-	-	-	Tracheostomy	-	-
17	ThulasiDoss	54	MALE	Toxicology	07-05-16	6	07-05-16	5	-	-	-	-	Tracheostomy	-	-
18	Deepa	16	FEMALE	Toxicology	15-03-17	6	15-03-17	6	continued	-	-	-	Tracheostomy	-	-
19	Sivalingam	53	MALE	Toxicology	22-12-16	8	22-12-16	7	continued	-	Yes	-	Tracheostomy	-	-
20	Prakash	35	MALE	RTA	30-10-16	8	30-10-16	7	continued	-	-	-	Tracheostomy	-	-

SL NO	NAME	AGE	SEX	NEW Diaganosis	DOA	GCS 1	DOI	GCS 3	Intubation Continued / Weaned	DOW	Re Intubation	DOD	INTN_TRACH	DOE	OUTCOME
21	Natarajan	61	MALE	Neurological	15-09-16	7	15-09-16	7	continued	-	-	-	Tracheostomy	-	-
22	Gnanaprakash	28	MALE	Toxicology	30-12-16	9	31-12-16	8	continued	-	-	-	Tracheostomy	-	-
23	Mani	55	MALE	Toxicology	20-12-16	8	20-12-16	7	continued	-	-	-	Tracheostomy	-	-
24	Prabhu	26	MALE	Neurological	08-10-16	8	08-10-16	7	continued	-	-	-	Tracheostomy	-	-
25	Ramaya	30	MALE	Toxicology	20-12-16	8	20-12-16	8	Continued	-	-	-	Tracheostomy	-	-
26	Muniyammal	60	FEMALE	Medical	02-12-16	8	02-12-16	7	Continued	-	-	-	Tracheostomy	-	-
27	Anandharaj	60	MALE	Toxicology	31-12-16	8	31-12-16	7	Continued	-	-	-	Tracheostomy	-	-
28	Dharman	70	MALE	Toxicology	19-12-16	8	19-12-16	8	continued	-	-	-	Tracheostomy	-	-
29	Velmurugan	39	MALE	Toxicology	02-01-17	7	02-01-17	7	Continued	-	-	-	Tracheostomy	-	-
30	Shanmugam	29	MALE	Toxicology	17-03-17	6	17-03-17	5	continued	-	-	-	Tracheostomy	-	-
31	Ayesha Siddique	24	FEMALE	Toxicology	14-01-16	9	15-01-16	8	continued	-	-	-	Tracheostomy	-	-
32	DhanaLekshmi	60	FEMALE	Neurological	02-01-17	6	02-01-17	6	continued	-	-	-	Tracheostomy	-	EXPIRED
33	Kathavarayan	55	MALE	Neurological	07-03-17	3	07-03-17	6	continued	-	Yes	-	Tracheostomy	-	Poor
34	Aruna	19	FEMALE	Neurological	29-12-16	8	30-12-16	7	Continued	-	Yes	-	Tracheostomy	-	-
35	Sivakumar	44	MALE	Neurological	26-12-16	5	26-12-16	5	continued	-	Yes	-	Tracheostomy	-	-
36	Gnanaprakasam	28	MALE	Toxicology	31-12-16	6	31-12-16	5	continued	-	-	-	Tracheostomy	-	-
37	Kumaresan	32	MALE	Toxicology	31-03-17	7	31-03-17	7	continued	-	Yes	-	Tracheostomy	-	-
38	Mahesh	38	MALE	Toxicology	01-05-16	8	01-05-16	3	-	-	-	-	Tracheostomy	-	-
39	Kumaresan	36	MALE	Toxicology	01-03-17	7	01-03-17	6	continued	-	-	-	Tracheostomy	-	-
40	Raja	39	MALE	RTA	20-04-17	9	23-04-17	7	continued	-	-	-	Tracheostomy	-	-
41	Devanai	40	FEMALE	Toxicology	13-03-17	6	13-03-17	6	continued	-	Yes	-	Tracheostomy	-	-
42	thenraj	66	MALE	Toxicology	09.06.16	6	9.6.2016	5	continued				tracheostomy		-
43	lakshmi	42	FEMALE	Toxicology	11.08.16	7	11.8.2016	6	continued				tracheostomy		-
44	dharmaraj	33	MALE	Neurological	23.07.16	5	23.7.2016	4	continued				tracheostomy		-
45	alex	27	MALE	RTA	23.02.17	6	23.2.2017	6	continued				tracheostomy		-
46	sheela	52	FEMALE	Toxicology	15.05.16	7	15.5.2016	6	continued				tracheostomy		-
47	BASHA	28	MALE	Toxicology	16.03.17	7	16.3.2017	6	continued				TRACHEOSTO MY		-
48	Sujatha	64	FEMALE	Neurological	09-07-16	5	09-07-16	6	continued	-	-	-	Tracheostomy	-	-
49	nadhya	24	FEMALE	Toxicology	18-08-16	7	18-08-16	7	continued	-	-	-	Tracheostomy	-	-

SL NO	NAME	AGE	SEX	NEW Diaganosis	DOA	GCS 1	DOI	GCS 3	Intubation Continued / Weaned	DOW	Re Intubation	DOD	INTN_TRACH	DOE	OUTCOME
50	Mahendran	50	MALE	Medical	20-09-16	7	20-09-16	7	continued	-	-	-	Tracheostomy	-	-
51	Muthu	59	MALE	Neurological	15-03-17	8	15-03-17	7	continued	-	-	-	Tracheostomy done on 25-03-17	-	-
52	Chandru	38	MALE	Neurological	20-02-17	7	20-02-17	5	continued	-	Yes	-	Trachestomy done on 05-03-17	-	-
53	Vennila	42	FEMALE	Medical	04-03-17	8	04-03-17	7	continued	-	Yes	-	Tracheostomy done on 14-3-17	-	-
54	Thangaraj	60	MALE	Medical	18-01-17	6	18-01-17	6	continued	-	-	-	tracheostomy done on 5-2-17	-	-
55	Chandra	38	MALE	Neurological	30-01-17	6	30-01-17	5	continued	-	-	-	tracheostomy done on 14-2-17	-	-
56	Mari	35	MALE	Toxicology	09-06-16	6	09-06-16	5	continued	-	Yes	-	tracheostomy done on 28-6-16	-	-
57	Dandapaani	49	MALE	Toxicology	28-02-17	6	28-02-17	7	continued	-	Yes	-	Tracheostomy	-	-
58	Ilayaraja	31	MALE	Toxicology	04-04-17	5	04-04-17	5	continued	-	-	-	Tracheostomy	-	-
59	Karpaga Lekshmi	37	FEMALE	Toxicology	20-12-16	9	31-12-16	7	continued	-	Yes	-	Tracheostomy	-	ventilator asso pneumonia (+)
60	Dhakshanamoorthy	28	MALE	Toxicology	05-11-16	7	05-11-16	6	continued	-	Yes	-	Tracheostomy	-	-
61	Kannan	55	MALE	Neurological	07-11-16	6	07-11-16	5	continued	-	Yes	-	Tracheostomy	-	-
62	Varatharajan	53	MALE	Neurological	16-01-17	8	16-01-17	5	continued	-	-	-	Tracheostomy	-	-
63	Kalidoss	45	MALE	Medical	14-01-17	8	14-01-17	6	continued	-	-	-	22-01-17	-	-
64	Baskar	55	MALE	Medical	08-01-17	7	08-01-17	6	continued	-	Yes	-	Tracheostomy	-	-
65	Surya Prabha	62	FEMALE	Neurological	13-12-16	8	14-12-16	6	continued	-	Yes	-	Tracheostomy	-	-
66	Mayil	35	FEMALE	RTA	30-12-16	8	30-12-16	7	continued	-	-	-	Tracheostomy	-	-
67	Chinnammal	60	FEMALE	Neurological	20-12-16	6	20-12-16	6	continued	-	Yes	-	Tracheostomy	-	-
68	Rajendran	58	MALE	Neurological	06-11-16	7	06-11-16	7	continued	-	-	-	Tracheostomy	-	-
69	Vasanth	52	FEMALE	Neurological	30-11-16	5	30-11-16	5	continued	-	Yes	-	Tracheostomy	-	-
70	elumalai	36	MALE	Toxicology	20-06-16	7	20-06-16	7	continued	-	-	-	Tracheostomy	-	-
71	Ramkumar	28	MALE	Toxicology	18-02-17	7	18-02-17	6	continued	-	-	AMA on 20-02-17	Apollo Hospital Intubation Continued	-	Denied Trachestomy for 10 days
72	Radhika	22	FEMALE	Toxicology	06-01-17	8	06-01-17	6	continued	-	Yes	-	Tracheostomy	-	Poor

SL NO	NAME	AGE	SEX	NEW Diaganosis	DOA	GCS 1	DOI	GCS 3	Intubation Continued / Weaned	DOW	Re Intubation	DOD	INTN_TRACH	DOE	OUTCOME
73	Kasi	55	MALE	Toxicology	15-08-16	6	15-08-16	5	continued	-	Yes	-	continued	05-09-16	Improved
74	Palani	26	MALE	Toxicology	23-09-16	6	23-09-16	5	continued	-	-	08-10-16	-	-	-
75	Ramya	21	FEMALE	Toxicology	20-05-16	6	20-05-16	5	continued	-	-	-	continued	02-06-16	Improved
76	Prabhu	20	MALE	Toxicology	10-07-16	7	10-07-16	7	continued	-	-	-	continued	20-07-16	discharged
77	Kalaivanam	20	MALE	Toxicology	14-03-17	6	14-03-17	6	continued	-	-	-	Continued	26-03-17	Improved
78	Manimaran	22	MALE	Toxicology	26-03-17	8	27-03-17	5	continued	-	Yes	-	Continued	10-04-17	Improved
79	Guruvayarappan	32	MALE	Toxicology	11-04-17	7	11-04-17	7	continued	19-04-17	Yes	22-04-17	-	23-04-17	Improved
80	Naveen Kumar	18	MALE	Toxicology	08-04-17	5	08-04-17	3	continued	-	-	-	-	-	EXPIRED
81	Jaiganesh	35	MALE	Medical	18-04-17	7	18-04-17	6	continued	-	Yes	-	Continued	-	EXPIRED
82	Valli	48	FEMALE	Neurological	02-05-16	6	02-05-16	3	continued	-	-	-	Continued	-	EXPIRED
83	Ambika	23	FEMALE	Medical	03-08-16	6	03-08-16	5	continued	-	-	-	Continued	15-08-16	Improved
84	Ashok Kumar	32	MALE	Neurological	18-01-17	7	18-01-17	6	-	-	-	-	-	-	-
85	Guganathan	60	MALE	Neurological	09-02-17	8	09-02-17	6	Continued	-	Yes	-	Continued	16-02-17	Improved
86	Guganathan	60	MALE	Neurological	09-02-17	8	09-02-17	6	Continued	-	Yes	-	Continued	16-02-17	Improved
87	Kumar	55	MALE	Toxicology	23-04-16	8	23-04-16	11	continued	28-04-16	no	-	-	-	-
88	Rukmani	60	FEMALE	Medical	12-03-17	5	12-03-17	3	continued	-	Yes	-	Continued	-	EXPIRED
89	Stella Mary	23	FEMALE	Toxicology	17-02-17	8	18-02-17	7	continued	-	Yes	-	Continued	26-02-17	Improved
90	Markus Bala	22	MALE	Toxicology	07-07-16	8	07-07-16	8	continued	-	Yes	-	Continued	20-07-16	Improved
91	Murugan	55	MALE	Toxicology	11.2.17	7	11-02-17	8	continued	-	Yes	-	Continued	16-02-17	-
92	Kamatchi	30	FEMALE	Toxicology	28-06-16	8	28-06-16	8	continued	-	Yes	-	Continued	04-07-16	Improved
93	Kannan	32	MALE	Toxicology	28-04-17	5	28-04-17	4	continued	-	Yes	-	Continued	-	EXPIRED
94	Kayan	40	MALE	Toxicology	14-07-16	7	14-07-16	7	continued	-	no	-	Continued	19-07-16	Improved
95	Ramu	40	MALE	Toxicology	17-05-17	7	17-05-16	7	continued	22-05-17	-	-	-	-	-
96	Kowsalya	25	FEMALE	Toxicology	06-06-16	8	06-06-16	12	continued	10-06-16	-	10-06-16	-	-	Improved
97	Velu	22	MALE	Toxicology	16-02-17	8	16-02-17	8	continued	-	Yes	-	Continued	25-02-17	Improved
98	Raji	37	MALE	Toxicology	03-06-16	8	03-06-16	10	-	17-06-16	-	19-06-16	-	-	Improved
99	Rajasekar	21	MALE	Toxicology	19-07-16	8	19-07-16	10	continued	23-07-16	Yes	-	-	-	Improved
100	Beera Chandran	40	MALE	RTA	07-02-17	7	07-02-17	6	Continued	-	-	AMA on 11-02-2017	-	-	-

... MASTER CHART (2) Continued

SL NO	NAME	DOT	REASON_TRACH	IOC	D.O.W.A.TR	D.O.M. CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
1	Issac	28-03-17	respiratory insufficiency	-	04-04-17	08-04-17	05-04-17	11-04-17	15-04-17	Improved	Normal	Normal
2	Vijaya	12-09-16	Prolonged Ventilation	-	26-09-16	03-10-16	02-10-16	07-10-16	10-10-16	Improved	Normal	Normal
3	Divya	30-06-16	Tracheo-Broncheal Toileting	-	05-06-16	42528	10-06-16	13-07-16	15-07-16	Improved	Normal	normal
4	Narayanasamy	03-03-17	Prolonged Ventilation	-	26-03-17	28-03-17	05-04-17	10-04-17	12-04-17	Improved	Normal	Normal
5	Santhrika	10-06-16	respiratory insufficiency	-	22-06-16	30-06-16	24-06-16	05-07-17	06-07-17	Improved	Normal	Normal
6	Murugan	14-02-17	Prolonged Ventilation	-	22-02-17	26-02-17	25-02-17	01-03-17	02-03-17	Improved	Normal	Normal
7	Shanmugavelu	04-03-17	Prolonged Ventilation	-	10-03-17	13-03-17	13-03-17	16-03-17	21-03-17	Improved	Normal	Normal
8	Narayanasamy	07-03-17	respiratory insufficiency	-	11-03-17	13-03-17	14-03-17	16-03-17	17-03-17	Improved	Normal	Normal
9	Sakunthala	07-03-17	respiratory insufficiency	-	12-03-17	15-03-17	14-03-17	20-03-17	21-03-17	Improved	Normal	Normal
10	Sivakumar	06-07-16	Prolonged Ventilation	-	11-07-16	13-07-16	13-07-16	15-07-16	17-07-16	Improved	Normal	Normal
11	Vinoth	18-03-17	Tracheo-Broncheal Toileting	-	22-03-17	22-03-17	25-03-17	25-03-17	26-03-17	Improved	Normal	Normal
12	Alamelu	02-04-17	Prolonged Ventilation	-	07-04-17	08-04-17	10-04-17	12-04-17	12-04-17	Improved	Normal	Normal
13	Annadurai	05-01-17	respiratory insufficiency	tube displacement	08-01-17	11-01-17	09-01-17	14-01-17	15-01-17	Improved	Normal	Normal
14	Suryakala	10-08-16	Prolonged Ventilation	-	18-08-16	23-08-16	20-08-16	30-08-16	02-09-16	Improved	Normal	Normal
15	Jeyakumar	24-10-2016	Tracheo-Broncheal Toileting	tube block	30-10-16	02-11-16	03-11-16	05-10-16	06-10-16	Improved	Normal	Normal
16	Madanraj	08-05-16	Tracheo-Broncheal Toileting	-	12-05-16	13-05-16	13-05-16	18-05-16	20-05-16	Improved	Normal	Normal
17	ThulasiDoss	09-05-16	Prolonged Ventilation	-	21-05-16	-	23-05-16	-	discharged with Shiley's tube at request on	Improved	expired	Expired
18	Deepa	20-03-17	-	-	23-03-17	24-03-17	24-03-17	27-03-17	28-03-17	Improved	Normal	Normal
19	Sivalingam	25-12-16	Tracheo-Broncheal Toileting	tube block	30-12-16	03-01-17	31-12-16	05-01-17	05-01-17	Improved	Normal	Normal

SL NO	NAME	DOT	REASON_TR ACH	IOC	D.O.W.A.TR	D.O.M. CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
20	Prakash	03-10-16	Prolonged Ventilation	-	06-10-15	07-10-16	06-10-16	09-10-16	09-10-16	Improved	Normal	Normal
21	Natarajan	19-09-16	Prolonged Ventilation	-	23-09-16	25-09-16	23-09-16	26-09-16	26-09-16	Improved	Normal	Normal
22	Gnanaprakash	03-01-17	respiratory insufficiency	-	05-01-17	07-01-17	06-01-17	10-01-17	10-01-17	Improved	Normal	Normal
23	Mani	24-12-16	Tracheo- Broncheal Toiletting	-	26-12-16	27-12-16	26-12-16	30-12-16	30-12-16	Improved	Normal	Normal
24	Prabhu	11-10-16	respiratory insufficiency	-	14-10-16	15-10-16	14-10-16	17-10-16	18-10-16	Improved	Normal	Normal
25	Ramaya	24-12-16	respiratory insufficiency	-	26-12-16	28-12-16	26-12-16	31-12-16	02-01-17	Improved	Normal	Normal
26	Muniyammal	06-12-16	respiratory insufficiency	-	09-12-16	09-12-16	10-12-16	12-12-16	12-12-16	Improved	Normal	Normal
27	Anandharaj	03-01-17	Tracheo- Broncheal Toiletting	tube block	06-01-16	07-01-16	06-01-16	10-01-16	10-01-16	Improved	Normal	Normal
28	Dharman	21-12-17	Tracheo- Broncheal Toiletting	-	25-12-17	30-12-17	27-12-17	03-01-17	03-01-17	Improved	Normal	Normal
29	Velmurugan	08-01-17	Tracheo- Broncheal Toiletting	-	12-01-17	14-01-17	12-01-17	16-01-17	17-01-17	Improved	Normal	Normal
30	Shanmugam	20-03-17	respiratory insufficiency	-	26-03-17	28-03-17	27-03-17	02-04-17	02-04-17	Improved	Normal	Normal
31	Ayesha Siddique	17-01-16	respiratory insufficiency	-	22-01-16	23-01-16	23-01-16	26-01-16	26-01-16	Improved	Normal	Normal
32	DhanaLekshmi	06-01-17	respiratory insufficiency	-	20-01-17	26-01-17	27-01-17	30-01-17	31-01-17	Improved	Expired	Expired
33	Kathavarayan	13-03-17	respiratory insufficiency	-	18-03-17	19-03-17	19-03-17	-	Discharged with Metallic Tube	Resudial Paralysis	Normal	Treacheostoma Ulceration
34	Aruna	06-01-17	respiratory insufficiency	-	12-01-17	15-01-17	13-01-17	16-01-17	17-01-17	Improved	Normal	Normal
35	Sivakumar	02-01-17	Prolonged Ventilation	-	-	-	-	-	-	Expired on 15- 01-2017	Expired	Expired
36	Gnanaprakasam	03-01-17	respiratory insufficiency	-	-	-	-	-	-	Expired on 27- 01-2017, HIE/AKI/Resp. Failure	Expired	Expired
37	Kumaresan	08-04-16	Prolonged Ventilation	-	19-04-16	22-04-16	22-04-16	27-04-16	27-04-16	Improved	Normal	Secondary Suturing Done
38	Mahesh	03-05-16	respiratory insufficiency	-	expired	-	-	-	-	Expired	Expired	Expired
39	Kumaresan	07-03-17	Tracheo- Broncheal Toiletting	Bleeding (+)	09-03-17	11-03-17	11-03-17	11-03-17	43,072	Improved	Normal	Normal

SL NO	NAME	DOT	REASON_TRACH	IOC	D.O.W.A.TR	D.O.M.CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
40	Raja	28-04-17	Prolonged Ventilation	-	08-05-17	12-05-17	15-05-17	-	21-05-17	Improved	Normal	Normal
41	Devanai	23-03-17	Prolonged Ventilation	-	28-03-17	01-04-17	-	03-04-17	03-04-17	Improved	Supraglottic Mucosal Injury Present	Normal
42	thenraj	13-06-16	Prolonged Ventilation	-	Expired on 22-06-16					Expired	Expired	Expired
43	lakshmi	14.8.2016	respiratory insufficiency	-	19.8.2016	22.8.2016	23.8.2016	25.8.2016	26.8.2016	improved	normal	normal
44	dharmaraj	26.3.2016	Prolonged Ventilation	-	31.7.2016	6.8.2017	12.8.2016	20.8.2016	22.8.2016	improved	Normal	Normal
45	alex	27.2.2017	Prolonged Ventilation	-	12.3.2017	14.3.2017	16.3.2017	24.3.2017	24.3.2017	Improved	Normal	Normal
46	sheela	19.5.2016	respiratory insufficiency	tube block	28.5.2016	31.5.2016	3.6.2016	4.6.2016	6.6.2016	Improved	Normal	Normal
47	BASHA	21.3.2017	Tracheo-Broncheal Toiletting	-	27.3.2017	28.3.2017	29.3.2017	3.4.2017	4.4.2017	Improved	Normal	Normal
48	Sujatha	26-07-16	Prolonged Ventilation	tube block	07-08-16	16-08-16	23-08-16	06-09-16	08-09-16	Improved	Normal	Normal
49	nadhya	03-09-16	Tracheo-Broncheal Toiletting	-	09-09-16	13-09-16	10-09-16	16-09-16	17-09-16	Improved	Normal	Normal
50	Mahendran	02-10-16	Prolonged Ventilation	-	17-10-16	21-10-16	22-10-16	25-10-16	26-10-16	Improved	Normal	Normal
51	Muthu	25-03-17	respiratory insufficiency	-	07-04-17	12-04-17	10-04-17	-	15-04-2017 Discharged with metallic tube	Improved	with metallic tube	Strapping
52	Chandru	05-03-17	Prolonged Ventilation	-	16-03-17	21-03-17	22-03-17	-	28-03-2017 with metallic tube	Improved	Normal	Expired
53	Vennila	14-03-17	Prolonged Ventilation	-	12-04-17	20-04-17	19-04-17	25-04-17	26-04-17	Improved	Normal	Normal
54	Thangaraj	05-02-17	Prolonged Ventilation	-	28-02-17	06-03-17	05-03-17	10-03-17	10-317	Improved	Normal	Normal
55	Chandra	14-02-17	Prolonged Ventilation	bleeding from tracheostomy site	-	-	-	-	-	expired on 28-2-17	Expired	Expired
56	Mari	28-06-16	Prolonged Ventilation	-	11-07-16	15-07-16	17-07-16	21-07-16	23-07-16	Improved	Normal	Normal
57	Dandapaani	10-03-17	Prolonged Ventilation	-	25-03-17	29-03-17	26-03-17	04-04-17	05-04-17	Improved	glottic injury, VC edema (+)	Normal
58	Ilayaraja	11-04-17	Prolonged Ventilation	-	28-04-17	29-04-17	29-04-17	05-05-17	06-05-17	Improved	presented with stridor, tracheal stenosis on 4-6-17	tracheal resection of anastomosis done on 28-6-17

SL NO	NAME	DOT	REASON_TRACH	IOC	D.O.W.A.TR	D.O.M. CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
59	Karpaga Lekshmi	03-01-17	Prolonged Ventilation	-	08-02-17	-	12-02-17	-	discharged with Shiley's tube	Expired	expired on 5-4-17	Expired
60	Dhakshanamoorthy	15-11-16	Prolonged Ventilation	-	30-11-16	03-12-16	02-12-16	06-12-16	08-12-16	Improved	L VC ulceration	Normal
61	Kannan	15-11-16	Prolonged Ventilation	-	expired on 2	-	-	-	-	expired on 2-12-16	Expired	Expired
62	Varatharajan	31-01-17	Prolonged Ventilation	-	-	-	-	-	-	expired on 15-2-17	Expired	Expired
63	Kalidoss	22-01-17	respiratory insufficiency	-	18-02-17	21-02-17	20-02-17	-	discharged with metallic tube	Improved	Normal	strapped
64	Baskar	17-01-17	Prolonged Ventilation	-	06-02-17	10-02-17	06-02-17	14-02-17	14-02-17	Improved	Normal	Normal
65	Surya Prabha	23-12-16	Prolonged Ventilation	-	16-01-16	17-01-16	16-01-16	20-01-16	22-01-16	Improved	Normal	Normal
66	Mayil	07-01-17	Prolonged Ventilation	tube displacement	22-01-17	26-01-17	24-01-17	30-01-17	31-01-17	Improved	Normal	Normal
67	Chinnammal	02-01-17	respiratory insufficiency	tube displacement	25-01-17	28-01-17	25-01-17	-	Discharged with Metallic Tube	Improved	Normal	strapping
68	Rajendran	15-11-16	Prolonged Ventilation	-	28-11-16	05-12-16	28-11-16	-	Discharged with Metallic Tube	residual paresis (+)	Normal	Normal
69	Vasanth	12-02-17	respiratory insufficiency	-	-	-	-	-	-	Expired on 13-12-2016	Expired	Expired
70	elumalai	29-06-16	Tracheo-Broncheal Toiletting	-	15-07-16	16-07-16	16-07-16	-	Discharged with Metallic Tube	Improved	Improved	Treacheostoma Ulceration
71	Ramkumar	05-03-17	Tracheo-Broncheal Toiletting	-	09-03-17	13-03-17	14-03-17	15-03-17	15-03-17	Improved	B/L Vocal cord injury (+) Glottic	Normal
72	Radhika	15-01-17	Tracheo-Broncheal Toiletting	-	20-01-17	24-01-17	25-01-17	01-02-17	02-02-17	Complication	Subglottic Web	Same Status
73	Kasi	-	-	-	-	-	-	-	08-09-16	Improved	20-10-16, tracheostomy done (tracheal stenosis)	on metallic tube-normal
74	Palani	-	-	-	-	-	-	-	08-10-16	Improved	glottic stenosis, tracheostomy on 24-11-16	metallic tracheostomy tube
75	Ramya	-	-	-	-	-	-	-	05-06-16	Improved	subglottic stenosis, tracheostomy done on 10-11-16	on metallic tube 19-1-16
76	Prabhu	-	-	-	-	-	-	-	23-07-16	Improved	glottic web tracheostomy on 12-9-16	Normal

SL NO	NAME	DOT	REASON_TRACH	IOC	D.O.W.A.TR	D.O.M. CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
77	Kalaivanam	-	-	-	-	-	-	-	26-03-17	Improved	subglottic stenosis, stridor on 8-4-17	Shiley's tube til date
78	Manimaran	-	-	-	-	-	-	-	13-04-17	Complication	tracheal stenosis, presented with stridor on 30-4-17	on metallic tracheostomy tube
79	Guruvayarappan	-	-	-	-	-	25-04-17	-	28-04-17	Improved	glottic injury, anterior synechiae	minimal synechaea
80	Naveen Kumar	-	-	-	-	-	-	-	-	expired on 16-4-17 (HIE/Respiratory failure)	Expired	Expired
81	Jaiganesh	-	-	-	-	-	-	-	-	expired on 29-4-17, (sepsis/MOD S/ Respiratory insufficiency)	Expired	Expired
82	Valli	-	-	-	-	-	-	-	-	expired on 15-5-17 (Acute metabolic encephalopathy/ respiratory failurte	Expired	Expired
83	Ambika	-	-	-	-	-	17-08-16	-	19-08-16	Improved	Normal	Normal
84	Ashok Kumar	-	-	-	-	-	03-02-17	-	-	Improved	Normal	Normal
85	Guganathan	-	-	-	-	-	-	-	18-02-17	Improved	Glottic Injury	Normal
86	Guganathan	-	-	-	-	-	-	-	18-02-17	Improved	Glottic Injury	Normal
87	Kumar	-	-	-	-	-	29-04-16	-	30-04-16	Improved	Normal	Normal
88	Rukmani	-	-	-	-	-	-	-	-	Expired	Expired	Expired
89	Stella Mary	-	-	-	-	-	-	-	27-02-17	Improved	Supraglottic Mucosal Injury Present	Normal
90	Markus Bala	-	-	-	-	-	20-07-16	-	22-07-16	Improved	dysphagia, supraglottic mucosal injury	Normal
91	Murugan	-	-	-	-	-	18-02-17	-	20-02-17	Improved	Glottic Injury, L VC ulceration present	Normal
92	Kamatchi	-	-	-	-	-	04-07-16	-	42,497	Improved	Glottic Injury, R VC injury present	Normal
93	Kannan	-	-	-	-	-	-	-	-	Expired	Expired	Expired
94	Kayan	-	-	-	-	-	20-07-16	-	21-07-16	Improved	voice change, post commisure injury	Normal

SL NO	NAME	DOT	REASON_TR ACH	IOC	D.O.W.A.TR	D.O.M. CHANGE	D.O.TR.	D.O.S.	D.O.D.A.T	OUTCOME DISCHARGE	VDL1	VDL2
95	Ramu	-	-	-	-	-	22-05-16	-	23-05-16	Improved	Supraglottic Mucosal Injury Present	Normal
96	Kowsalya	-	-	-	-	-	-	-	-	Improved	Normal	Normal
97	Velu	-	-	-	-	-	28-02-17	-	28-02-17	Improved	Supraglottic Mucosal Injury Present	Normal
98	Raji	-	-	-	-	-	-	-	42,619	Improved	Normal	Normal
99	Rajasekar	-	-	-	-	-	24-07-16		26-07-16	Improved	Normal	Normal
100	Beera Chandran	-	-	-	-	-	-	-	-	Expired	Expired	Expired

KEYS TO MASTER CHART

DOA	-	DATE OF ADMISSION
GCS	-	GLASGOW COMA SCALE
DOI	-	DATE OF INTUBATION
DOW	-	DATE OF WEANING
DOD	-	DATE OF DISCHARGE AFTER INTUBATION
DOE	-	DATE OF EXTUBATION
DOT	-	DATE OF TRACHEOSTOMY
REASON_TRACH	-	REASON FOR TRACHEOSTOMY
IOC	-	INTRA OPERATIVE COMPLICATIONS
D.O.W.A.TR	-	DATE OF WEANING AFTER TRACHEOSTOMY
D.O.M CHANGE	-	DATE OF METALLIC TUBE CHANGE
D.O.TR	-	DATE OF TRANSFER OUT
D.O.D.A.T	-	DATE OF DISCHARGE AFTER TRACHEOSTOMY
VDL1	-	VIDEOLARYNGOSCOPY WITHIN ONE MONTH AFTER DISCHARGE
VDL2	-	VIDEOLARYNGOSCOPY SIX MONTHS AFTER DISCHARGE

**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.G.Parimala Devi
Post Graduate in M.S. E.N.T.
Upgraded Institute of Otorhinolaryngology
Madras Medical College
Chennai 600 003

Dear Dr.G.Parimala Devi,

The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARATIVE STUDY ON PROLONGED ENDOTRACHEAL INTUBATION VERSUS TRACHEOSTOMY IN TOXICOLOGY PATIENTS REQUIRING PROLONGED MECHANICAL VENTILATION" - NO.10012017 (IV).**

The following members of Ethics Committee were present in the meeting hold on **31.01.2017** conducted at Madras Medical College, Chennai 3

1.Dr.C.Rajendran, MD.,	:Chairperson
2.Dr.M.K.Muralidharan,MS.,M.Ch.,Dean, MMC,Ch-3	:Deputy Chairperson
3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	: Member Secretary
4.Prof.B.Vasanthi,MD., Prof.of Pharmacology.,MMC,Ch-3	: Member
5.Prof.S.Suresh,MS, Prof. of Surgery,MMC,Ch-3	: Member
6.Prof.N.Gopalakrishnan,MD,Director,Inst.of Nephrology,MMC,Ch	: Member
7.Prof.S.Mayilvahanan,MD,Director, Inst. of Int.Med,MMC, Ch-3	: Member
8.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person
9.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

PROFORMA

NAME

AGE/SEX

DIAGNOSIS

PHONE NUMBER

D.O.A

GCS ON DAY 1

D.O.INT

GCS ON DAY 3

SBT

PaO₂/FiO₂ RATIO

RESPIRATORY RATE

RAPID SHALLOW BREATHING INDEX

INTUBATION CONT/WEANED

D.O.WEANING

REINTUBATION

D.O.DISCHARGE

INTN CONTD/TRACH

D.O.EXT

OUTCOME

D.O.TRACH

REASON FOR TRACH

INTRA OP COMPL

D.O.WEANING AFTER TRACH

D.O.METALLIC TUBE CHANGE

D.O.TRANSFER OUT

D.O.STRAPPING

D.O.DISCHARGE

OUTCOME

VDL1

VDL2

INFORMATION SHEET

- We are conducting **A COMPARATIVE STUDY ON PROLONGED ENDOTRACHEAL INTUBATION VERSUS TRACHEOSTOMY IN TOXICOLOGY ICU PATIENTS REQUIRING PROLONGED MECHANICAL VENTILATION** at the Upgraded Institute of Otorhinolaryngology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 600003.
- Tracheostomy reduces work of breathing, reduces anatomical dead space and promotes early weaning from mechanical ventilation
- At the time of announcing the results and suggestions, name and identity of the patients will be confidential.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator

Date :

Signature of Participant

PATIENT CONSENT FORM

**Title of the Project : A COMPARATIVE STUDY ON PROLONGED
ENDOTRACHEAL INTUBATION VERSUS TRACHEOSTOMY IN
TOXICOLOGY ICU PATIENTS REQUIRING PROLONGED MECHANICAL
VENTILATION**

Institution : Upgraded Institute of Otorhinolaryngology,
Madras Medical College,
Chennai – 600003.

Name : _____ Date : _____
Age : _____ IP No. : _____
Sex : _____ Project Patient No. : _____

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study.

_____	_____	_____
Name of the subject	Signature	Date

_____	_____	_____
Name of the Investigator	Signature	Date

ஆராய்ச்சி தகவல்தாள்

சென்னை ராஜீவ் காந்தி அரசு பொது மருத்துவமனையில் “மூச்சுக்குழாயில் துளையிடுதல் (Tracheostomy) மற்றும் பெருமூச்சுக்குழலுக்குள் நீடித்த குழாய் செருகுதல் (Prolonged Endotracheal Intubation) பற்றிய ஒப்பீட்டு ஆய்வு”.

இந்த ஆராய்ச்சியில் மூச்சுக்குழாயில் துளையிடுவதால் நோயாளிகளுக்கு சுவாச வேலை குறைவதோடு மருத்துவமனையில் இருக்கும் காலம் குறைக்க முடியும்.

பெருமூச்சுக்குழலுக்குள் நீடித்த குழாய் செருகுதலால் வரும் பின்விளைவுகளும் மற்றும் மூச்சுக்குழாயில் துளையிடுவதால் வரும் பின்விளைவுகளும் ஒப்பீட்டு ஆராயப்பட உள்ளது.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆய்வின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த ஆய்வில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில்தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆய்விலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆய்வின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆய்வாளரின் கையொப்பம்
தேதி

பங்கேற்பாளர் கையொப்பம்

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு

மூச்சுக்குழாயில் துளையிடுதல் (Tracheostomy) மற்றும் பெருமூச்சு குழலுக்குள்
நீடித்த குழால் செருகுதல் பற்றிய ஒப்பீட்டு ஆய்வு

ஆய்வு நிலையம் : ராஜீவ் காந்தி அரசு பொது மருத்துவமனை,
சென்னை மருத்துவக் கல்லூரி, சென்னை.

பங்கு பெறுவரின் பெயர் : உறவுமுறை:

பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு
விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த
விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த
காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான்
இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்
போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை
பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில்
இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை
முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர்
மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு
மனதுடன் சம்மதிக்கின்றேன்.

☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட
அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும்
மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன்.

☐

பங்கேற்பவரின் கையொப்பம் இடம்..... தேதி.....

கட்டைவிரல் ரேகை:

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் இடம்..... தேதி.....

ஆய்வாளரின் பெயர்

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